Food Safety and the Diffusion of Federal Regulation

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Much has been written regarding the contracting out of public services and the consequent management challenges for government administrators. Intergovernmental programs, administered jointly by the federal government and states, generate significant contracting/outsourcing activity. Much of this manifests in the area of social welfare policy through contracts for services and case management for welfare to work programs, child welfare, Medicaid, and SCHIP. The recently implemented Affordable Care Act – the largest social welfare innovation in decades – also relies heavily on contracts, including those for the notorious health exchange problems experienced by the federal government and several states.

Our research focuses on an emerging phenomenon in outsourcing and federalism: the contracting out of core federal regulatory duties to states. Regulatory activity related to food safety - specifically, food safety inspections – is diffusing from the U.S. Food and Drug Administration (FDA) to states via contracts in a phenomenon that has been referred to in other policy arenas as “contractual devolution” (Nathan and Gais 1998). In this case, the contractual devolution involves regulation, which has traditionally been conducted by the federal government. We view this development in intergovernmental devolution as one that is important from a variety of perspectives – political, administrative, economic. We explore the phenomenon with a focus on the responses of federal and state managers charged with ensuring the safety of the nation’s food supplies. The research described in this paper is the first stage of a larger study that will examine broader implications for contracting, regulatory policy, and the relationship between federal and state level actors.
This stage of analysis draws on data gathered from 28 semi-structured interviews with 31 food safety actors, supplemented with document reviews. Interviews are continuing; we report here on interview data collected between January 2013 and March 2014 with directors and staff from food safety programs in thirteen states that contract with FDA. Additional interviews were conducted with six FDA managers responsible for managing contracts and other partnerships with state counterparts, two senior FDA officials responsible for shaping policy, and a senior investigator in the Health and Human Services (HHS) Office of the Inspector General (OIG) regarding their recent investigation of FDA’s contracts with states. In addition, interviews were conducted with stakeholders from national consumer protection groups, experts in food safety and government contracting from the U.S. Government Accountability Office (GAO), and the Executive Director of a nongovernmental professional organization whose membership is comprised mostly of state-level food safety officials, and which represents the interests of food regulatory agencies in Congress and elsewhere.

We began the interview process with the goal of learning how FDA altered its management of contracts with states in response to a 2011 Health and Human Services Office of Inspector General report on major gaps in FDA’s oversight of its state contracts (see discussion below). The topic of state contract inspections was consistently cited by our interview respondents as a central concern, due in part to attention and criticism directed at states following the landmark 2011 OIG

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investigation, but also due to a mandate contained in recent federal legislation that requires FDA to dramatically increase the number of annual domestic inspections. The FDA, according to our interviews and other documents, intends to meet this mandate primarily through state contracts.

Following an inducted, grounded theory approach (Glaser & Strauss 1967; see also Sandfort 2000), our analysis has confirmed that devolution of regulation via contracts to states is a significant phenomenon that is changing the landscape of food safety and national regulatory policy. Notably, this development has received relatively scant scholarly attention. We have begun to identify patterns and key variables that we will explore in greater depth as our research progresses. The interviews also allowed us to observe ways in which federal and state officials are both driving and responding to this decentralization of regulation. We will use these data to generate protocols for future interviews, to develop testable hypotheses regarding regulatory contractual devolution, its key dynamics, variations in its manifestations and impacts, and to explore its implications for federal regulation of food safety and other policy arenas.

As states assume the primary responsibility for federal domestic food safety inspections, the FDA’s role is increasingly concerned primarily with oversight and policymaking. At the same time, Congress, responding to growing concerns about the safety of imported food, has recently adopted legislation authorizing the FDA to rely on “third parties” – e.g. the states and/or their contractual delegates - for inspections of foreign firms. In short, in both the domestic and international arenas, federal food safety regulation is increasingly outsourced to other governments and
also, through the state contracts, to nongovernmental entities, with FDA managing these relationships “from a distance.” We see this new system as somewhat comparable to Milward and Provan’s (2000) hollow state, and their concept of a “systems integration function,” which emerges when government has contracted out most of its core functions and shifts primarily to a focus on “monitoring and evaluating contracts” (362).²

While Milward and Provan were describing the contracting out of government services to the private sector, we believe their description is applicable to the dynamics of contracting out regulatory inspections to states. As FDA relies more and more on states to conduct regulatory inspections, the agency function in this area has narrowed to two primary functions: (1) managing contracts and (2) setting and implementing policies that attempt to establish consistency among states. Several states contract out all or some portion of selected inspections to nongovernmental organizations, adding complexity to the accountability process for this regulatory function. Furthermore, our interviews and document analysis reveal that, in spite of a centralized contracting process, FDA is limited in its oversight capacity for a variety of reasons; many of these reasons are discussed in subsequent sections of this paper.

**States as Contractual Agents: Reviewing the Literature**

A review of the literature in contracting, federalism, and networks reveals several common themes that can provide a theoretical framework from which to

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² Contracting with nongovernmental entities merits attention, and is the subject of some of our related research but the primary focus of this paper is on FDA contracts with states.
examine this particular mode of contractual devolution in the context of food safety regulation. Much has been written about bureaucracy and the nature of public bureaucratic organizations, with many characterizations pointing to the inflexible and slow-to-change nature of such organizations, especially those in the federal government (Blau 1955, Albrow 1970, Kamenka 1989). Indeed, the classic Weberian image of the “Iron Cage” of bureaucracy seems to be the abiding image of large federal bureaucracies in the United States. Owing in part to this image, as well as a commonly held belief in the inherent competitive advantages of the free market, there is often an assumption that the private sector can “do it better,” “it” being the provision of public services (Buchanan 1972). Milward and Provan (2000) coined the phrase “hollow state” to describe both the “increasing reliance of the public sector on contracting with nonprofit agencies and for-profit firms for the delivery of taxpayer funded goods and services,” as well as the “degree of separation between a government and the services it funds—i.e. the number of layers between the source and the use of funds” (362). Furthermore, “carried to an extreme it refers to a government that as a matter of public policy has chosen to contract out all its production capability to third parties, perhaps retaining only a systems integration function that is responsible for negotiating, monitoring, and evaluating contracts” (ibid.).

Many scholars have pointed to important differences between the government and private sector that should be taken into account in the context of contracting. Hefetz and Warner (2012) argue that, as a service provider, the government, unlike the private sector, is responsible for ensuring probity, which
they define as failsafe service delivery. In their view, “probity” captures the idea that government and public managers are beholden to – and servants of - the public interest and the public good. Along these lines, Johnston and Romzek (2010) examine outsourcing trends and propose challenges to the deep-seated assumption that the private sector is a more efficient substitute for government provision of services. Price and Ricucci’s (2005) review of decisions to privatize state prisons reveals that such decisions often tend to be politically motivated, rather than driven by actual efficiency gains, and Singer (2007) starkly illustrates the pitfalls of what many see as an increasing overreliance on private contractors for the core responsibilities of government, including national defense. These authors point out that market rationales for contracting are often weak at best, and that contracting increasingly is the default option, despite serious market weaknesses in some service areas.

At the same time, Bevir (2010) argues that the hollow state has the potential to increase, rather than decrease, government control over civil society and the private sector, creating a situation in which government is more effective and exercises more extensive control than a traditional bureaucratic state; he contrasts this model with traditional Weberian forms of bureaucracy, with their emphases on command and control hierarchies. Ironically, many public choice scholars, as well as proponents of contracting, would not favor increasing government control, even in this indirect form. In their view, reliance on markets for government service delivery reduces government monopoly and inefficiency.
Regardless of the normative position one takes, it is undeniable that the growing reliance on contracting has created a situation in which federal managers are increasingly responsible for managing and overseeing contracts and the contracting process, rather than carrying out service-oriented work (Johnston and Girth 2012).

The federal government also relies increasingly on networks of actors, including states, non-profit organizations, and others, to carry out its duties. A central concern raised by many has to do with whether this trend enhances effective governance. Milward and Provan (2000) define governance as a collection of mechanisms or tools that create the “conditions for ordered rule and collective action” (360). Such mechanisms can include grants, contracts, and agreements, and includes non-governmental actors operating in the non-and-for-profit sectors, as well as traditional civil servants. These mechanisms vary in their degree of formality (e.g. from formal contracts to less formal memoranda of understanding), or the “degree to which they (the networks) operate autonomously or are steered by the state” (ibid). Governance can also refer to the various structures through which networks of actors are connected and coordinated to serve public ends.

Kenis and Provan (2007) distinguish between governance of organizations and governance of networks, suggesting that the latter requires a less traditionally bureaucratic model of management and decision-making. Similarly, Stazyk et al (2011) stress the importance of managing networks in government contracting and intergovernmental collaboration, noting that networks “offer an alternative to managerial hierarchies and pure market exchanges” (3). As historians like Theda
Skocpol (1995) demonstrate, formal and informal networks of service providers have existed in the United States for quite some time. Tracing the roots of modern social welfare programs, Skocpol shows that public services evolved through the interplay of a complex network of multi-level federal, state, local, and non-government entities. While these early stages led to formal institutionalization of provision of services at the federal level, she demonstrates that the various organizations in these networks continued to operate in a complicated interrelationship throughout the nineteenth and twentieth centuries, to the present day.

There is a substantial body of research that highlights and examines various challenges in managing networks and contracts in a variety of areas such as: non-profit nursing homes (Amirkhanyan et al 2008), local transit systems (Zullo 2008), child welfare and other social welfare systems (Johnston and Romzek 2008), and mental health systems Milward et al 2010). Some of these challenges are related to the transaction costs inherent in network management (Williamson 1999; Frederickson and Stazyk 2010; Johnston and Romzek 2010).

Many network scholars note the lessons for network management that can be drawn from the literatures on federalism and devolution (Agranoff and McGuire 2004; Bird 1993, Soss et al 2001, Krane 2004). However, there is comparatively little research that examines these issues in the area of federal regulatory policy. One exception is the area of environmental policy; we know, for instance, that the federal government has devolved significant environmental responsibilities to the states, including the implementation and enforcement of key federal statutes such
as the Clean Water Act. This decentralization has taken a variety of forms. Potoski and Woods (2002) remind us that political priorities and existing state environmental and regulatory policies are likely to be important determinants of a given state's post-devolution environmental policy decisions. Sigman (2003) describes the phenomenon of “authorization,” a status granted to states by the Environmental Protection Agency (EPA) that gives states the legal authority – and responsibility - to implement, monitor, and enforce federal environmental regulations. She argues that this practice represents the most significant form of decentralization of environmental policy. Accordingly, federal environmental programs should not be treated (or evaluated) as uniform, since the practice of granting states authorization may result in significant differences across programs. This is due to the fact that authorization grants states a large degree of discretion, which leads to variation in the level of stringency of regulation. Soss, Fording and Schram (2008) and others have observed similar dynamics in the area of social welfare policy, with traditionally conservative states crafting the most conservative policies after devolution while traditionally liberal states tend to exhibit more generous policies with higher benefit levels and wider sets of benefits. Early comprehensive federalism research conducted by Plotnick and Winters (1985) remind us that state policy decisions are driven by a large and complicated set of factors related to economic, political, and demographic profiles.

Decentralization of regulatory responsibilities can therefore lead to substantial variation in the enforcement of federal environmental statutes (Flatt 1997, Farber 1997), with potentially weaker enforcement in states with close ties to
industry. Another school of thought suggests that granting states greater authority leads to more robust enforcement of regulations (Revesz 2001). Empirical investigations into this question are mixed in their conclusions: for instance, Helland (1998) finds a weak but statistically significant positive correlation between authorization and outcomes of environmental inspections, wherein states with greater authorization authority tended to have better inspections outcomes (i.e. more firms passing inspections). However, Helland also concluded that the stringency of compliance inspections conducted by state agencies may be moderated by budgetary and political forces, such as a state agency’s “industry friendliness,” calling into question the conclusions that one should draw from higher inspection “pass” rates. Sigman (2003) reminds us that empirical studies are limited in their ability to make causal claims; for example, it could be that states with stronger environmental programs are those that are in fact granted more authorization authority. More troubling is the prospect that some states may take a more lax approach to inspections and enforcement, resulting in the false appearance of compliance.

These literatures lead us to the following question: To what extent are regulatory responsibilities devolving to states, and is there reason to believe that states can strengthen food safety regulation? What actions are federal and state managers adopting in response to the devolution of food safety regulation activities? Does interstate variation in food safety enforcement practices threaten the integrity of our food supply? We believe our study helps to shed some light on these areas of inquiry.
The Newly Crucial Role of States: Federal Regulation and Food Safety

While Americans enjoy a relatively safe food supply, the Centers for Disease Control and Prevention (CDC) estimate that 76 million Americans get sick annually due to unsafe food products; 325,000 of them are hospitalized, and 5,000 die from foodborne hazards.\(^3\) The number and scale of multi-state outbreaks of foodborne illness is increasing: to illustrate, 550 people from 19 states were sickened this past summer by the parasite Cyclospora, which was traced to packaged salad produced in Mexico\(^4\). FDA is responsible for ensuring the safety and quality of 80 percent of the American food supply, including $417 billion of value in domestic food and $49 billion in imported food annually.\(^5\) Federal regulation of food safety was nonexistent until the early part of the twentieth century. A Progressive-era reform effort was aided by the famous 1906 publication of Upton Sinclair’s book *The Jungle*, an expose of horrific and unsanitary conditions in the Chicago meatpacking industry. The *Pure Food and Drugs Act* was passed within the same year, with the primary aim of enabling the government to act “after the fact, against blatant, reckless deception” by food suppliers. It also established the Bureau of Chemistry, which became the FDA in 1938, with the passage of the *Food, Drug, and Cosmetics Act*.

Though hard-won, federal regulation of food safety has been subject to much criticism, often from within the food industry, but also from members of Congress.

\(^4\) This case helps us understand why FDA is shifting focus to foreign inspections and relying on states to do domestic inspections: the “guilty” Mexican firm had only ever had one inspection by FDA - back in 2001 - despite being a major exporter to the US. GAO, *Federal Oversight of Food Safety: FDA has Provided Few Details on the Resources and Strategies Needed to Implement Its Food Protection Plan*, GAO-08-909T (Washington, D.C.: June 12, 2008). USDA is responsible for the other 20 percent, but contracts out very little of its regulatory functions. Future research will compare these two agencies and explore reasons for these differences.
who criticize FDA variously for doing too much - or not enough. In his history of the agency, Paul Quirk (1980) observes that the “balance of external forces impinging on the FDA is not a constant. It fluctuates with events, with the rise and decline of social movements and political organizations, with experience of the impact of previous regulatory decisions, and with broad changes of public attitude...There are significant pressures on the FDA to regulate both strictly and leniently” (193).

At a national level, the responsibility to ensure food safety lies squarely with FDA, which has a statutory requirement to enforce food safety laws and regulations via inspections and other activities (see Quirk 1980, and Hinich and Staelin 1980). FDA is required by law to conduct a certain number of domestic food facility inspections per year. Since 2009, over half of FDA inspections have been conducted by state agencies acting under contract with FDA. This number and proportion has been steadily increasing, a trend which is expected to continue. According to our interview respondents, FDA began pursuing contracts with states as a way to meet annual inspections requirements (described as “performance standards”) set by Congressional appropriators; the appropriators specified that if FDA did not complete a certain number of annual inspections, the agency's budget would be cut. Some states have been performing contract inspections for over a decade, while others have only begun doing so in the last few years. Concerns have been raised in recent years regarding the rigor of some state inspections, especially following revelations that the peanut processing plant responsible for a 2009 outbreak of salmonella was inspected multiple times by a state agency working under contract with FDA and was awarded a clean bill of health.
The peanut incident prompted Congress to mandate that the HHS OIG carry out a systematic review of FDA’s contractual relationships with states. Congress complained that, “this outbreak...leads to serious questions about the effectiveness of state food facility inspections and FDA’s ability to oversee its contracts with states.”6 The 2011 OIG report found that the rate of contracting out to states has increased significantly over the last decade, with well over half of FDA inspections now carried out by state agencies.7 Table 1 confirms this, providing data on the number of food facilities inspected by FDA since 2004 (decreasing), and those facilities inspected by states under contract to FDA (significant increase).8 Specifically, the OIG found that the overall number of facilities inspected has decreased from just over 17,000 facilities in FY 2004 to just under 16,000 (15,900) in FY 2009.9 This represents a significant increase in the percentage of facilities inspected by states under contract with FDA; in fiscal year (FY) 2009, 59 percent of FDA’s food inspections were conducted by state inspectors, compared to only 42 percent in FY 2004.10

Our interviews with state officials further confirmed this trend and indicate a rapid acceleration. Each person we interviewed stated that the number of FDA contracts has dramatically increased since 2009; for instance, one state has moved from conducting “2 or 3” contract inspections in 2009 to more than 50 contract inspections.

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6 OIG 2011, p. 194.  
7 Department of Health and Human Services Office of Inspector General, Vulnerabilities in FDA’s Oversight of State Food Facility Inspections, OEI-02-09-00430 (Washington, D.C.; December 2011).  
8 Ibid. p.10  
9 Ibid, p. 2.  
10 Ibid. p.3
inspections in 2012-2013. Our interview data are firmly consistent: each interviewed official fully expects this trend to continue.

Table 1. Food Facilities Inspected by FDA and by States Under Contract With FDA, FYs 2004-2009

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Number of Food Facilities Inspected</th>
<th>Number of Food Facilities Inspected by FDA</th>
<th>Number of Food Facilities Inspected by States Under FDA Contract</th>
<th>Percentage of Food Facilities Inspected by States</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>17,032</td>
<td>10,354</td>
<td>7,073</td>
<td>42%</td>
</tr>
<tr>
<td>2005</td>
<td>15,773</td>
<td>8,247</td>
<td>7,828</td>
<td>50%</td>
</tr>
<tr>
<td>2006</td>
<td>14,547</td>
<td>7,065</td>
<td>7,695</td>
<td>53%</td>
</tr>
<tr>
<td>2007</td>
<td>14,418</td>
<td>6,118</td>
<td>8,506</td>
<td>59%</td>
</tr>
<tr>
<td>2008</td>
<td>15,055</td>
<td>6,209</td>
<td>9,050</td>
<td>60%</td>
</tr>
<tr>
<td>2009</td>
<td>15,920</td>
<td>6,796</td>
<td>9,430</td>
<td>59%</td>
</tr>
</tbody>
</table>

Note: The number of facilities inspected by FDA and the number of facilities inspected by States are not mutually exclusive and therefore do not sum to the total number of facilities inspected. On average, 271 facilities were inspected by both FDA and States in each FY.


At about the same time that these concerns were being investigated by the OIG, Congress passed the 2011 Food and Drug Modernization Act (FSMA), which significantly increases federal reliance on states. FSMA contains a mandate that FDA increase the number of annual inspections - though an exact number is not specified in the Act itself - and explicitly authorizes the agency to utilize counterpart agencies in order to meet this requirement:

"Beginning on the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall increase the frequency of inspection of all facilities... In meeting the inspection requirements under this subsection for domestic facilities, the Secretary may rely on inspections conducted by other Federal, State, or local agencies under interagency agreement, contract, memoranda of understanding, or other obligation."

11 Precise data on the current number of contracts has been requested from FDA but is not yet available.
12 Table excerpted from OIG report, p. 10.
13 FSMA, Section 201, E (ii), p. 124.
According to interviewed FDA officials, this increase will be accomplished primarily by expanding the number and scope of state contracts. In addition to increasing inspections of domestic facilities, FSMA mandates an exponential increase in inspections of overseas facilities – the number of foreign facilities inspected must double each year.\textsuperscript{14} Several high-profile incidents of foodborne illness traced back to imported food motivated this mandate.

The FDA and state officials we interviewed told us that FDA is shifting the majority of its domestic inspection responsibilities to states in large part to free FDA inspectors to focus their attention abroad.\textsuperscript{15} As noted above, concerns about the safety of imported food continued to mount this summer in the wake of an outbreak of the parasitic disease \textit{Cyclosporiasis}. This incident was traced back to packaged salad produced at a facility in Mexico, which the FDA had inspected only once, in 2001, despite its role as a major supplier to several popular U.S. restaurant chains, such as Ruby Tuesday and The Olive Garden. This incident – which illustrates the high salience of food safety failures - has once again renewed pressure on FDA to increase the number of overseas inspections. While this intensification is a requirement of the new legislation, FDA has struggled to implement it due to resource constraints.

It remains to be seen how FDA will meet this challenge, but it seems certain that an important component is the growth in reliance on states to meet domestic inspection requirements. As one senior state official put it, FDA is “never going to get enough money to do the work (mandated by FSMA) themselves” and will have to

\textsuperscript{14} FSMA, Section 201, D (i, ii), p. 124.

\textsuperscript{15}
rely on states, and in the case of imported food, private third parties. A senior FDA official cautioned that, “FSMA is a huge step forward, but we need the money to implement it.” Another senior official has publicly referred to the lack of funding needed to comply with the new law as “the FSMA funding gap,” estimated at $225 million. Another FDA official told us that FDA requested Congress to fund an additional 1,000 full-time equivalent (FTE) employees to meet the new inspections mandate. Because Congress denied the request, the FDA is all but forced to outsource the inspections.

States have their own laws and regulations pertaining to food safety, and they conduct their own regulatory inspections. They have also been responsible for ensuring state food safety policy compliance with federal regulations. Variations in state food safety policies, however, create complexities. For example, one interviewed state official cited policies related to raw, unpasteurized milk certain states, such as Oregon and Pennsylvania, permit the selling of this product; federal law, however, prohibits interstate trade of this product. Hence, state-level inspections must take both sets of regulations into account, depending on where the product is to be sold – information which is not always available. States conducting inspections under contract with FDA must take these policy differences into account, which can be very costly in terms of administrative resources.

**Contract Management and State Variations**

Our interview respondents reported consistently that the costs of inspections are much lower for states. This is due to a variety of factors, including lower
comparatively low state costs for travel and personnel. For example, a food safety official from a large Western state pointed out that his state inspectors are located throughout the state and can reach a facility faster – and at lower cost – than an FDA inspector who may be based many times the distance away. Additionally, a large determinant of the cost per inspection is personnel costs, and state inspectors are paid less than FDA inspectors on average, according to our interviewees. Another important difference between FDA and state inspections is the time and amount of documentation involved. Many of the officials we interviewed remarked that inspections conducted by FDA tend to be very time-intensive, particularly with regard to the required paperwork after the actual physical inspections are conducted. One state official said that it takes "weeks" for an FDA inspector to prepare an inspection report, compared to "one or two days" for a state inspector, and several described the FDA process as "burdensome" and "overly bureaucratic."

Importantly, this differential in processing costs relates to reduced reporting requirements for states: when states conduct inspections for FDA under contract, they are not required to follow the FDA process, including documentation requirements. As one state official put it, states are "basically doing our own inspections," but getting paid by FDA. This results in far less time spent per inspection, which drives costs down even further. According to FDA officials, differences in federal and state law mostly exempt state agencies from having to document inspections results at the same level of detail as FDA. This is because states tend to have far more stringent food safety laws than FDA, an explanation that may appear counterintuitive; however, in this case, greater legal authority comes
with reduced red tape. For example, most states are able to place an immediate embargo (or “stop sale”) on a company if a state inspector has credible belief that there may be contamination in a food production facility, while federal law requires FDA to obtain a court order to do so. The court order involves a time- and paperwork-intensive process, with all of the accompanying rules of evidence, and is the main reason that FDA inspectors must spend so much time documenting their inspections – as one interviewee put it, they are essentially “building a hypothetical legal case” every time they conduct an inspection, even if no such case ever arises. However, another FDA official noted that this difference also means that FDA inspectors take more time conducting inspections, collecting evidence and extensive data that may prove invaluable in the event of an outbreak of foodborne illness and ensuing court case.

Several interviewed state and FDA officials cited advantages and reasons beyond cost savings for outsourcing inspections to states. Key among these was the observation – familiar to students of fiscal federalism and decentralization - that state inspectors tend to more familiar with the industries within their states, and hence bring greater knowledge to the table than FDA inspectors who may not even be located in the state where the inspections take place. One state inspector told us that it is very common for FDA to request inspections of facilities that are no longer in operation, or that have been sold or relocated; hence, state inspectors have “institutional knowledge” that FDA inspectors lack, since they are based in the state and focus their work exclusively within state borders. Furthermore, FDA is organized into numerous regional and district offices, some of which span several
states. An FDA inspector whose office is in one state may therefore be responsible for inspections in a neighboring state. This not only contributes to costs (e.g. time spent traveling and related expenses), but also often means that FDA inspectors must have knowledge of the food industries and firms within several states. State inspectors, on the other hand, are only responsible for the firms within their state and hence may be more knowledgeable. As one state inspector put it, “It’s better to do things locally.” Another state official argued that states can do the “same work more effectively and cheaper” than FDA. These dynamics are consistent with the theoretical arguments for devolution: the level of government that best understands a jurisdiction’s needs and contexts is best suited to deliver more “efficient” services.

Despite these potential advantages, many of our interview respondents pointed out that there are significant differences in states’ regulatory capacities that may undermine the benefits of assigning states primary responsibility for regulatory inspections. A concern cited by some FDA officials is that some states may not be conducting inspections at the same level of rigor that an FDA inspector would – as one FDA official put it, state inspectors “should not leave their state inspector hats on when they go do an FDA inspection” because the FDA would approach the same inspection with higher standards. Each year, states are required by their own laws to conduct a certain number of food safety inspections. State inspectors might be responsible for conducting thousands of inspections per year, while FDA may only be responsible for a fraction of inspections in the same state. These workload variations may result in different approaches to inspections, with
states spending perhaps only one or two hours conducting an inspection. By comparison, the FDA may spend several days inspecting a single firm, and up to two weeks to complete the required documentation associated with the inspection. Because of this, as one FDA official put it, it is possible that many state contract inspections are not being conducted with the same degree of attention as an FDA inspection. In other words, the two inspection models are not interchangeable.

Recognizing this, FDA has taken steps to oversee contracts more closely and also has enacted policies that attempt to address discrepancies between state and FDA inspections, as well as differences between states. For example, following the 2011 OIG report, FDA began requiring states to submit quarterly, rather than annual, inspections reports. However, these reports do not include details about how the inspections were conducted – only that they were conducted and the results of the inspections. The agency also strengthened its Contract Audit Program; seven percent of state inspections are now accompanied by an FDA state liaison/auditor who observes the inspection as it is conducted and provides feedback to the state. However, as one FDA liaison observed, inspectors might behave differently if they are being audited, so there is no guarantee that these inspections represent the norm.

States vary considerably on a number of other dimensions related to regulating food safety, including regulatory and political culture, resource and budget constraints, historical and structural features, economic and industry contexts, and consequent incentives. For example, some states do not have a large
food manufacturing industry and hence their regulatory framework for food is minimal.

The structures of states’ regulatory systems may be especially important to ensuring food safety. For example, many states’ food safety programs are housed in the state Department of Agriculture, while others are operated by Departments of Health. These seemingly simple distinctions have important implications for food safety, regulatory policy, and contract management.

Consumer advocates have emphasized that FDA inspections are often contracted out to state Departments of Agriculture, which historically have been focused on the promotion of trade, not food safety. The food programs within many state Departments of Agriculture are primarily tasked with marketing state industries and commodities, and there is a concern that this may undermine a focus on food safety, compared to that which one might expect from state Departments of Health, which tend to have greater expertise related to epidemiology and other food-safety areas. A senior official from a state Department of Health told us that his department is essentially a “mirror image” of FDA, and that, in his experience, there tends to be a “clear conflict of interest” in state Departments of Agriculture that are charged both with promoting agriculture and regulating food safety. While this conflict is not necessarily evident at the “ground level” – i.e. in the quality and rigor of inspections – this official observed that there are competing interests that play out at the level of policymaking and the political arena, where the interests of industry can be very influential in many states.
Officials from state Departments of Agriculture disagree, in our interviews, with the suggestion that they might prioritize promoting trade over ensuring food safety, although their own characterization of how they approach food safety regulation suggests a difference between their approach and that of FDA. As officials from one “Department of Agriculture” state put it, “We educate before we regulate,” preferring to not use what they see as “punitive” measures favored by the FDA, but instead “working with” industry to help companies come into compliance with regulations. Another state official said that industry views the FDA as being like “the police,” and that many state agencies tend to take a much more collaborative approach to regulation.

Of course, it is important to remember that, in addition to affecting public health, outbreaks of foodborne illness can have significant economic ramifications for states. For example, the Georgia peanut industry was all but destroyed by the 2009 outbreak, representing a huge economic loss for the state. In other words, economic interests could benefit from stronger – not weaker – regulatory actions. Interestingly, one change that resulted from the outbreak was that the Georgia Department of Agriculture was granted far greater punitive authority, including the ability to levy civil penalties on companies that do not comply with certain state reporting requirements, exceeding authorities possessed by the FDA at that time. While they have not yet exercised this particular authority, Georgia officials we spoke to said it plays an important deterrent effect on would-be “bad apples.”

Finally, in addition to these differences between departments within states, state officials and consumer advocates pointed out to us that some states have very
sophisticated food safety programs due to unique circumstances that might be
difficult to replicate elsewhere: for example, the University of Minnesota has a very
strong, internationally recognized program in epidemiology, and the state benefits
from a close partnership with the university. New York has historically had a large
immigrant community and many retail establishments catering to this population,
and hence state health officials have been focused on imported food safety decades
before this became a national issue – in fact, New York is serving as a model for FDA
as the agency restructures its approach to regulating imported food. On the other
hand, fiscally strained states, many of which have comparatively low residential
income, generate less state revenue, with little funding available to develop robust
food safety programs.

Related to this is the role of industry fees at the state and federal levels. Most
state Departments of Agriculture collect fees from industry for market “grading”
services. To illustrate, the egg industry pays for a “Grade A” designation, which is
based mostly on market-based criteria such as appearance and size, but with some
considerations of safety and “good manufacturing practices” taken into account.
Most states cannot collect industry fees for regulatory safety inspections.

Historically, while FDA has collected industry (“user”) fees for certain services, most
inspection costs have been borne by the agency.16 The Food Safety Modernization
Act changes this by granting FDA authority to require firms to pay for inspections in
cases where the firms have failed initial routine inspections. These “re-inspection”
fees are seen by FDA as an important step toward shifting the cost of “high risk”

16 While over half of the FDA’s annual budget is funded by user fees, these overwhelmingly come
from the pharmaceutical, cosmetics, and medical devices industries.
inspections to industry and acting as a potential deterrent to safety violations.

According to some officials we interviewed, it also makes it more likely that a state will “turn over” an investigation to FDA if the state believes a firm should be held liable for the cost of inspections – rather than using state resources, states have a new incentive to collaborate with FDA.

Our interview and document review data therefore suggest that, as in other policy arenas, the “price of federalism” (Peterson 1995) emerges – in this case, as variations in the protection of citizens from unsafe food. State officials cited numerous examples of unique challenges within their states, but emphasized that resources, including training, are the key factors that determine a state’s ability to effectively carry out food safety inspections. States will of course vary with regard to their willingness to fund robust food safety programs and their tolerance for regulatory activity.

According to FDA officials, the agency is making a concerted effort to address these discrepancies between states, primarily through a program called the “Manufactured Food Regulatory Program Standards” (MFRPS). This is a voluntary program in which states opt to enroll; in doing so, they agree to implement numerous FDA standards and submit to periodic audits by FDA to ensure that these standards are being properly implemented. A senior FDA official told us that enrollment in MFRPS is now a requirement for all states that contract with FDA. It is not clear, however, whether this is indeed a formal requirement at this point, since a subsequent interview with a state official responsible for overseeing the state’s contract with FDA told us that, to his knowledge, enrollment in MFRPS is not yet
mandatory. This official also expressed doubts that MFRPS will actually lead to improvements in state programs, stating that the program is mostly “busy work.” FDA, however, sees MFRPS as a way to ensure a baseline national standard across states’ food safety programs. The program is in some ways analogous to the “primacy” movements in environmental policy that increased autonomy to those states willing to craft state implementation plans (SIPs) consistent with federal standards. Enrollment in MFRPS also generates some federal grants, and includes both opportunities and requirements for state officials to receive training from FDA.

At present, according to FDA, forty-one states are enrolled in MFRPS, although they vary widely in terms of what stage they are in their adoption of the program. Officials from several states cited their participation in MFRPS as key in the development and improvement of their food safety program, and described the FDA audits as useful and welcomed.

However, some states are highly resistant to MFRPS, citing the loss of autonomy as a primary reason, along with an increased workload and training requirements that they view as unnecessary and onerous. One state official told us that his state “avoided” enrolling in MFRPS since it seemed like it would be “a lot of work” requiring a large amount of “documentation and report reviews.” As one FDA official put it, the goal of the program is not to create “cookie-cutter” uniformity across states, but for states to build comparably robust food safety programs that, at a minimum, meet FDA regulatory standards. In other words, FDA recognizes the benefits of some uniformity while tapping into innovative state practices we sometimes associate with the “laboratories of democracy.” Another FDA official said
the purpose of MFRPS is to gradually establish a minimum level of consistency, with
the ultimate aim of achieving what the agency calls a “national integrated food
safety system.” One state official argued that “strong states aren’t the issue,” and
that FDA should focus on bringing “weaker” and “higher risk” states up to par. Still
in its early stages, it remains to be seen how effective the program is in achieving
these goals.

Conclusion

Through our interviews and document reviews, we have found evidence of
devolving federal authority for food safety regulatory inspections to states via
contracts. As this occurs, FDA is taking on an increasingly “systems integration” and
oversight role, with states becoming the primary regulatory actors. One senior state
official framed it as an identity crisis, with FDA finding itself in the position of having
to decide “what kind of agency” it wants to be: an “inspection agency,” or an
“oversight, training, evaluation, auditing” agency. In other words, as he put it, “is
FDA willing to relinquish control over regulation and shift to an auditing approach?”
If the latter is the case – as our initial research suggests – then, according to this
official, the central challenge becomes ensuring – and being able to demonstrate –
that states are doing equivalent work, both to FDA as well as to other states. As he
put it, “how do we know we are on the same page?”

To some extent, these patterns resemble those observed in earlier devolution
iterations. Like “welfare devolution,” FDA policy cedes significant authority to the
states in order to facilitate tailored programs conducted by agencies closest to the
jurisdictional policy problem, and to generate innovation from which other states and the federal government can learn. However, food safety is a regulatory concern. Most regulatory devolution has occurred in the environmental arena, and much of it occurred some time ago.

Food safety inspection devolution provides an opportunity for a fresh look at the costs and benefits of decentralized governance and reliance on third party delivery. The salience of food safety failures is high. People can and do die quickly and in large numbers when the policy fails. This is a fundamentally different problem from the slow encroachment of environmental toxins or shifts in welfare benefits. Our question is therefore an important one: what are the implications of devolving food safety regulatory activity to states and other third parties? Will patterns of devolution dynamics observed in other policy areas hold in the food safety arena? If not, why not?

Concerns have been raised regarding FDA’s ability to effectively carry out its new contract oversight role. Moreover, we have identified concerns regarding the variations in the capacity of states to take on their new responsibility. Administrative capacity for contract oversight is hardly a new worry (Romzek and Johnston 2005; Van Slyke 2003) and is likely to surface as a problem for FDA. As this trend shows no sign of slowing – and indeed every sign of accelerating – the “Intergovernmental Management” (Wright, 1990) relationships between federal and state food safety officials become increasingly vital. As our research continues, we have modified our interview protocol to take into account findings to date, develop testable hypotheses to explain variations in the effectiveness of devolved
food safety inspections, and ultimately to develop a survey tool that will allow us to
gather data that will permit us to generalize beyond our current sample of states.

Our ultimate objective is to better understand how and why federal and state
managers are responding to this evolving situation in regulatory policy, to identify
strategies that are deemed most effective and why, and to help inform policymakers
responsible for these matters.
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