

Modeling Partial Agency Autonomy in Public-Health Policymaking

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This Article considers the conditions under which administrative agencies — particularly those with public health-related missions — may obtain partial autonomy from external interests or politicians. In the process, it critiques the proposition that administrative agencies in advanced industrialized countries such as the United States are routinely “captured” by external economic interests. Through case studies and the application of relevant theory from law and the study of political organization, the Article describes how agencies can produce a measure of autonomy by forging coalitions of stakeholders both internal and external to the agency, and considers how partial autonomy may be modeled as a strategic process involving decisions under uncertainty. The Article then investigates how American public-health agencies such as the Food and Drug Administration, the Food Safety Inspection Service, and the Centers for Disease Control have been able to use their partial autonomy to develop significant health policy innovations. Although agencies are by no means guaranteed even a partial degree of autonomy, they are nonetheless capable of affecting their political and legal environment, with consequences not only for public-health policy but also for the legitimacy of the nation-state.

INTRODUCTION

Government agencies operating in a pluralist system under American-style administrative procedures tend to face a persistent tension. On the one hand

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laws frequently entrust to agencies the power to protect public health and security; on the other hand our public law embeds those agencies in a political economy of constraints and influence that routinely threatens to restrain, paralyze, or distort their ostensible mission.¹ Together, these dynamics can frustrate agencies' pursuit of a host of defensible public health measures ranging from stricter food defense standards to measures against the marketing of alcohol to minors. Indeed, because agencies face such constraints and the (economic and political) stakes are so high, some observers claim it is all but impossible for an agency to avoid being essentially "captured" by private interests with a stake in the agency's work.² Problems may arise even when policymakers harbor starkly different views from those prevalent in the private sector, because agencies may lack the capacity to resist constraints imposed on them by interested parties.

Protecting the public's health is a core function of government agencies — from the Environmental Protection Agency's rules affecting the exposure of millions to particulate matter to the Food and Drug Administration's enforcement decisions policing food and drug safety. The stakes are high not only for individuals or families, but for nation-states and regions of the world. The 1919 flu pandemic infected 500,000,000 people and caused approximately 50,000,000 deaths worldwide,³ but even far milder disease outbreaks can wreak havoc nationally and internationally. The actions of public health agencies can also make or break companies and even industries, galvanizing private interest in shaping agency decisions on food and drug regulation, environmental protection, product safety, and public-health surveillance. Agency decisions hold major financial stakes for vaccine providers, drug companies, insurers — as well as armies and families. In particular, concentrated costs

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- 1 In this context, "political economy" refers to the mix of institutions, actors, and incentives that combine to make particular policy outcomes more or less likely to emerge.
 - 2 Some scholars imply that the "capture" of regulatory agencies in such a fashion is common, even pervasive. See, e.g., Samuel Huntington, *The Marasmus of the ICC: The Commission, the Railroads, and the Public Interest*, 61 *YALE L.J.* 467 (1952); John Kay, *Better a Distant Judge Than a Pliant Regulator*, *FIN. TIMES*, Nov. 3, 2010, at 13, available at <http://www.ft.com/cms/s/0/9d5357d0-e6b5-11df-99b3-00144feab49a.html#axzz2eTu81pSq>; J.J. Laffont & Jean Tirole, *The Politics of Government Decision-Making: A Theory of Capture*, 106 *Q.J. ECON.* 1089 (1991); George Stigler, *The Theory of Economic Regulation*, 2 *BELL J. ECON. & MGMT. SCI.* 3 (1971).
 - 3 See J.K. Taubenberger & D.M. Morens, *1918 Influenza: The Mother of All Pandemics*, *EMERGING INFECTIOUS DISEASES*, Jan. 2006, at 69, available at http://wwwnc.cdc.gov/eid/article/12/1/05-0979_article.htm.

can generate powerful incentives for corporations and other private interests in a pluralist, democratic system to thwart or water down reforms. If agencies systematically prove incapable of separating private interests from sensible public-health goals — even in a context as directly relevant to people’s lives as public health — then the legitimacy of the nation-state itself is undermined.

In this Article, I analyze the capacity of agencies to develop a measure of autonomy from politicians and organized interests. Whether agencies can successfully promote public health depends to a considerable degree on a critical factor that also shapes a nation’s ability to address its other major challenges: the capacity of agencies to execute intricate legal responsibilities without succumbing to “capture” by narrowly motivated private interests. While scholars have occasionally explored how agencies achieve a degree of autonomy, my focus here is more specific: on raising questions about a certain type of “capture” thesis that implicitly forecloses the possibility of autonomy; and elucidating, in the context of population health, some of the mechanisms through which partial autonomy could arise. I advance these arguments by offering a simple model of how autonomy might arise in health-related agencies, along with specific examples from where agencies with health-related missions appear to have achieved a measure of autonomy for policy innovation.⁴

To develop these ideas, I begin in Part I, by assessing the concept of “capture” and considering the circumstances under which agencies are subject to “capture” or forge at least a partial degree of autonomy. I also consider some strategies for modeling the phenomenon of partial agency autonomy and its relationship to both legal and political circumstances. Because the analysis suggests that partial autonomy is at plausible for agencies with health-related functions, I provide three recent examples of the implementation of public-health laws by federal government agencies. The first example, stressed in Part II, concerns the FDA’s more than decade-long effort to regulate tobacco, despite legal, political, and scientific challenges. The second example is discussed in Part III and describes how the U.S. Department of Agriculture’s Food Safety Inspection Service built an alliance with political appointees to impose new requirements for meat and poultry safety, overcoming opposition from industry. These two examples primarily showcase — as the model implies — how the capture thesis fails to account fully for public-health policy innovations. Finally, Part IV includes the third example, which trains attention on the ability of the Centers for Disease Control and Prevention to shape public-health outcomes through public-health surveillance. It illustrates

4 For a helpful discussion of the literature about, and the concept of, autonomy, see DANIEL P. CARPENTER, *THE FORGING OF BUREAUCRATIC AUTONOMY* (2001).

another feature of the model — the importance of reputation in forging sufficient autonomy for an agency. Together, these examples suggest the viability of partial autonomy, illustrate features and extensions of the simple partial autonomy model developed below, and demonstrate why partial autonomy can play an important role in a governmental system seeking to integrate technical knowledge and democratic responsiveness.

I. CAPTURE, INSTITUTIONAL CONSTRAINTS, AND APPROACHES TO MODELING PARTIAL AUTONOMY

A. The Capture Thesis

Persistent public health problems confront even the wealthiest and most advanced societies. In early twenty-first century America, for example, approximately 450,000 people die prematurely because of tobacco each year, and 47,000,000 people annually face illness because of contaminated food.⁵ The United States' response to these challenges depends not only on social behavior and market activity, but also on the laws and institutions that structure those activities.⁶ The probability of finding that a patty of ground beef grilled on the Fourth of July includes an undesired side order of deadly *Escherichia coli* 0157:H7 depends in no small measure on the successes and limitations of a system of governance linking lawmakers, agency and executive branch officials, civil society, and economic interests.

5 Regarding foodborne illness, see CTRS. FOR DISEASE CONTROL, CDC ESTIMATES OF FOODBORNE ILLNESS IN THE UNITED STATES (2011), available at <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html> (providing estimates indicating that roughly one in six Americans suffers from foodborne illness each year, of whom about 128,000 are hospitalized and 3000 die from foodborne disease). On smoking's toll, see Ctrs. for Disease Control, *Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses — United States 2000-2004*, 57 MORTALITY & MORBIDITY WKLY. REP. 1226 (2008), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm> (also noting productivity losses attributable to cigarette smoking in the range of a hundred billion dollars per year); see also CAL. EPA, PROPOSED IDENTIFICATION OF ENVIRONMENTAL TOBACCO SMOKE AS A TOXIC AIR CONTAMINANT (2005), available at <http://www.arb.ca.gov/regact/ets2006/ets2006.htm>.

6 See generally Lawrence O. Gostin, Scott Burris & Zita Lazzarini, *The Law and the Public's Health: A Study of Infectious Disease Law in the United States*, 99 COLUM. L. REV. 1, 59, 64 (1999).

Some actors undeniably engage with the regulatory process by crafting aggressive strategies to control agencies or undermine public health regulation.⁷ Scholars concerned about agency “capture” contend that the interests behind these strategies not only constrain agencies, but wield sufficient political and economic influence to systematically acquire control of an agency’s activities.⁸ In its strongest form, the capture thesis implies a strong claim about the efficacy of those efforts in a state that is institutionally complex and shaped by a variety of coalitions that emerge from pluralist politics. An environment in which public health officials are nonetheless all but certain victims of such capture would not only bode ill for the nation’s capacity to perform a core function of modern functioning nation-states, but also make it difficult to expect much from bureaus working on energy policy, telecommunications, or other fields further from widespread public attention.⁹

Even if one were reluctant to accept the strong version of the capture thesis, it is undeniable that agencies face a variety of political and legal constraints on their action.¹⁰ Lawmakers and senior executive branch officials often seek to, and sometimes succeed in, controlling agencies or at least restricting their capacity to pursue new initiatives. At the same time, private actors can discourage agency action. And few if any agencies — even those with formal juridical independence from direct political control — can operate for long without depending on congressional appropriations, esteem from opinion leaders, or some outside measure of support. Given these relationships between agencies (including public-health agencies) and the outside world, whatever capacity for independent policy innovation agencies achieve is probably best understood as “partial” autonomy from external political or economic actors rather than absolute independence.

7 See Todd Lewan, *Industry Watch: Dark Secrets of Tobacco Company Exposed*, 7 *TOBACCO CONTROL* 315 (1998).

8 See, e.g., Laffont & Tirole, *supra* note 2.

9 See CARPENTER, *supra* note 4.

10 Indeed, the very term “agency” runs the risk of casting aside important distinctions between senior political appointees, career civil servants in prominent positions, and lower-level employees engaged in routine tasks. I return to these distinctions below, but the idea that “agencies” as organizations are capable of driving policy may still be a useful metaphor in cases where an agency’s senior political leadership cements a motivated coalition of civil servants, overcomes potential opposition from agency rank-and-file employees, and is able to use reputational and bureaucratic resources throughout the agency to achieve policy changes.

B. Partial Autonomy

Partial autonomy is a situation in which agency officials take the principal role in achieving significant legal or policy changes in domains such as population health, and neither interest group dynamics nor control of the agency by politicians explains the outcome. When an agency has partial autonomy, its decision to implement a new regulatory rule or policy may occur despite initial opposition by or indifference from politicians. Instead, agencies may be able to mobilize coalitions of support among sympathetic policymakers, opinion leaders, and civil society organizations. Such coalitions can allow an agency to make the most of scarce resources such as legal authority, budgets, and agency officials' capacity to bolster a bureau's reputation through persuasive communication with the larger public. Despite the fact that agencies are neither unitary actors nor impervious to opposition from inside government or beyond it, they can form coalitions and deploy their resources strategically to become powerful actors in law and policy — actors whose choices may shape some of the state's fundamental attributes.

At the same time, agencies are also shaped by certain larger attributes of the state. In countries where formal legal arrangements tend to be followed rather than ignored, schemes designed to govern administrative action can make it easier or harder for agencies to turn broad, open-ended laws into regulatory rules or organizational structures embodying new policies. In the United States and many other advanced industrialized countries, these arrangements embody a certain tension, captured by two elements of American administrative law doctrine. One strand is prominent in the landmark *Schechter Poultry* decision, in which an expansive New Deal-era delegation of authority from lawmakers ran afoul in part because the authority ultimately was exercised by private actors with an economic stake in regulatory policy.¹¹ Even after *Schechter's* overarching non-delegation holding has been eviscerated by subsequent cases that take a more permissive view of broad legislative delegations, existing doctrine continues to emphasize the importance of agency independence from private interests in decisions such as those governing agency *ex parte* communications.¹² At the same time, however, public consultation and

11 A.L.A. *Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935).

12 *See Action for Children's Television v. FCC*, 852 F.2d 1332 (D.C. Cir. 1988) (discussing *ex parte* communications); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983) (discussing the role of reasoned decision making by agencies in the context of determining whether a change in a regulatory rule was "arbitrary and capricious"). The latter case is less explicitly focused on the permissible limits of external interference in agency decision making. Still, its focus is on the responsibility of the agency to engage in reasoned decision

participation — including by private actors with economic stakes in a particular regulatory decision — remains a core element of the administrative law framework governing agency action.¹³ The default expectation that prevails in federal and even state administrative law is that agencies need to be sensitive to external concerns.¹⁴ As agencies perform their statutory missions, they often face considerable challenges in threading the needle between avoiding excessive external control of the kind posited by capture theory and engaging in sufficient public consultation.

In the public health context, though, the conventional regulatory capture concept may turn out to be a poor guide to how agencies manage these dilemmas. Agencies capable of making appeals to technical competence and scientific expertise — particularly on matters of relatively widespread public concern such as public health — may develop an enhanced capacity to manage relationships with organized interests, civil society, and the larger public from a position of strength relative to other agencies or organizations shaping the policy process.¹⁵ Agencies may also benefit from a connection of their mandate to domains of human health that, at least in principle, evoke universalistic, valence-oriented concerns that are easier for the public to understand as technical matters involving the protection of health, rather than economically or culturally contested issues. Although a large number of agencies ranging from transportation regulators to housing bureaus may also have missions that bear some connection connected to human health, economic or cultural issues can still permeate their jurisdiction and complicate their reputational relationship with the public.¹⁶

making and to offer valid factual and policy rationales for its decisions rather than succumbing to the influence of external economic or political interests.

- 13 For another example of the continuing concern with public consultation and participation, see Peter H. Schuck & Steven Kochevar, *Reg Neg Redux: The Career of a Procedural Reform*, 15 THEORETICAL INQUIRIES L. 417 (2014).
- 14 See *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375, 393 (D.C. Cir. 1973), cert. denied, 417 U.S. 921 (1974); see also Ronald M. Levin, *Nonlegislative Rules and the Administrative Open Mind*, 41 DUKE L.J. 1497, 1501 n.19 (1992) (citing *Portland Cement Ass'n*, 486 F.2d); Jerry L. Mashaw & David L. Harfst, *Regulation and Legal Culture: The Case of Motor Vehicle Safety*, 4 YALE J. REG. 257, 282 (1987) (showing that agencies must respond to all serious dimensions of the problem raised in comments).
- 15 Cf. DANIEL CARPENTER, REPUTATION AND POWER (2010); Sheila Jasanoff, *Science's Influence*, 27 ISSUES SCI. & TECH. 9 (2010).
- 16 Hence a possible distinction between the EPA and ATF, on the one hand, and the CDC on the other.

More specifically, in contrast to organizations responsible for issues such as public housing or agriculture policy, public perceptions of an agency's reputation tend to favor a public organization's claims of expertise in the public health domain in a fashion difficult to achieve for officials at (for example) Transportation or Labor agencies. Admittedly, this reservoir of trust can grow as agencies build personnel and capacity capable of validating preexisting public perceptions, or it can dissipate to some degree in the wake of heavily criticized choices, such as the Centers for Disease Control and Prevention (CDC)'s response to the swine flu scare of the mid-1970s. In comparison to agencies with more conventional administrative functions, however, public-health agencies appear to begin with a reservoir of legitimacy reflecting the public's broad association of modern health policy with scientific expertise.¹⁷

C. Strategies for Modeling Partial Autonomy for Health Agencies

At least some historical examples may offer a *prima facie* basis for presuming that certain significant past developments in public policy fail to fit with the conventional regulatory capture story.¹⁸ In the pages that follow, however, I aim to provide a simple representation of some of the institutional mechanisms that might be involved when agencies achieve partial autonomy, and to highlight how the public health-related context might afford agencies a distinctive opportunity to forge partial autonomy. Over time, some degree of agency autonomy could help account for changes in policy that contribute to rising life expectancy and health conditions.¹⁹

Conventional capture theory does not devote much sustained attention to the nuances that might distinguish situations in which agencies legitimately seek external input. If anything, the examples of agency public health innovations discussed below show agencies fulfilling their legal responsibilities to incorporate external input while still (and largely independently) using their broad legal jurisdiction to drive policy innovation. Indeed, external input and the support of rank-and-file agency employees (rather than simply other political appointees) probably helped the agencies anticipate and in some cases mollify opposition. At a minimum, these examples suggest that the legally regulated endeavor of obtaining broad public input can coexist with

17 Daniel Carpenter, *Is Health Politics Different?*, 15 ANN. REV. POL. SCI. 287 (2012).

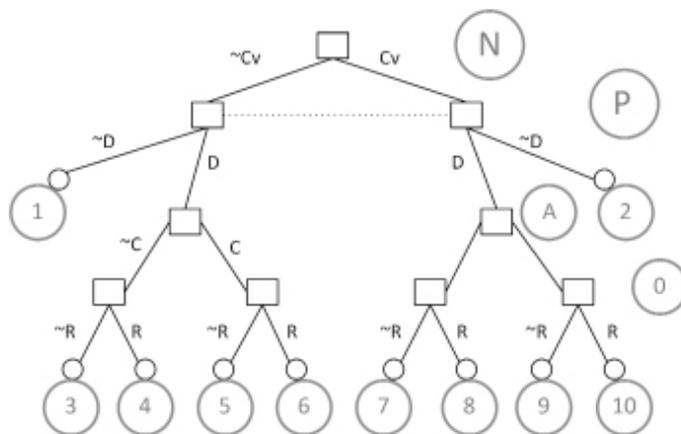
18 See, e.g., CARPENTER, *supra* note 4.

19 See Ctrs. for Disease Control and Prevention, *Ten Great Public Health Achievements — United States, 1900-1990*, 48 MORBIDITY & MORTALITY WKLY. REP. 1141 (1999).

another dynamic — one rooted in legal and policy concerns about the value of independence — whereby agencies resist control and develop significant public health reforms.

To see how such a process might unfold, it is helpful to start with a highly stylized but illustrative depiction of the world. Figure 1 describes a simple game embodying some of the essential attributes of a simple principal-agent relationship arising as an agency handles a specific policy issue.²⁰ An agency (A), a political coalition led by a politician (P), and a bevy of external interests outside government (O) compete to shape policy. The game begins with a move by “nature” (N) that determines whether the winning political coalition and the agency happen to have policy interests that are broadly aligned (C_v) or not aligned ($\sim C_v$) regarding how a given law should be implemented. The politician faces the conventional dilemma of principal-agent models: the more the politician believes those interests to be aligned, the more likely the politician will be to delegate authority to the agency (action D) rather than choosing not to delegate (action $\sim D$, thus ending the game at outcomes 1 and 2). If legal authority is in fact delegated, the agency then decides whether to act in accordance with the politician’s general views on questions of implementation (e.g., whether to expand occupational safety regulatory requirements, or whether to treat modified machinery as “new” sources of pollution, and so on). Action C thus denotes relative consistency with the politician’s views, while action $\sim C$ denotes relative inconsistency. As with lawmaking in the American system and many other countries, it is difficult to change existing laws; thus the agency could also seek to implement a policy that the politician rejects but nonetheless cannot necessarily reverse — though this course of action could understandably reduce the agency’s payoffs by exposing it to potential retaliation from the politician. Finally, an external interest can choose to retaliate and impose costs on the agency if the agency’s choice of policy deviates from the group’s preferred position (with R indicating the imposition of such costs, and $\sim R$ indicating no such imposition). Outcome 6, for example, would involve an agency with divergent views relative to the politician choosing to proceed with an innovative new policy but confronting costly resistance from an external group.

20 The notation for depicting games and information sets follows DAVID M. KREPS, *A COURSE IN MICROECONOMIC THEORY* (1990).

Figure 1: Simple Agency Delegation Game

In this depiction, the phenomenon of “capture” could arise from the chilling effect of the outside group’s credible threat to impose costs on the agency — costs that could include, for example, the risk of lost budgets or perhaps consequences for the career prospects of agency employees. If the agency sufficiently fears outcomes 4, 6, 8, and 10, it will conclude through backward induction that it should not choose those policies (whether C or $\sim C$) that would provoke retaliation from the outside group. Notice how even a simple depiction of a principal-agent problem cuts against treating “capture” as a default outcome — at least absent some clearer theoretical basis. In addition, the agency may simply fail to obtain the discretionary authority necessary to perform its putative mission effectively because the politician chooses not to delegate authority to the agency.

The prescriptive merits of these outcomes depend, of course, on the premise that the agency’s preferred policy is desirable. But for present purposes, notice what this simple depiction omits. It does not distinguish between agencies with different substantive responsibilities. Yet agencies with technically complex health-related responsibilities, for example, may have a claim to special deference from politicians and the general public given their perceived role in managing sensitive matters of high salience to the public.²¹ Following much of the conventional principal-agent literature, Figure 1 also treats the agency as a unitary actor.²² The strategic choices facing the agency, moreover,

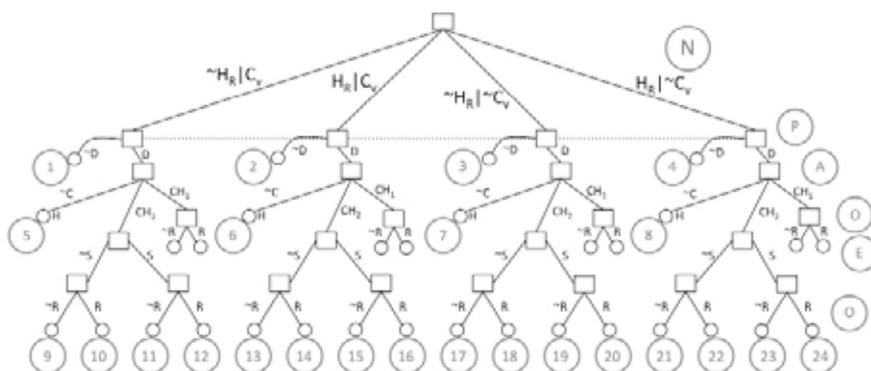
21 See, e.g., Carpenter, *supra* note 17.

22 See, e.g., Eric Maskin & Jean Tirole, *The Principal-Agent Relationship with an Informed Principal: The Case of Private Values*, 58 *ECONOMETRICA* 379 (1990).

leave no room for it to reshape its political environment by forging coalitions with actors inside or outside the executive branch — coalitions that could be capable of changing the agency’s political circumstances or modifying the laws it is implementing.

Now consider an alternative specification that introduces just a few more parameters, of the kind that may be relevant to how an administrative agency could forge partial autonomy. Figure 2 summarizes this alternative framework. In addition to the politician (P), this specification includes an agency leader (A), a representative of senior career agency officials (E), and external groups (O). At the outset, “nature” (N) determines whether the game proceeds along one of four different paths. As with Figure 1, the paths differ with respect to whether the agency leader’s views are aligned with those of the politician (C_v or $\sim C_v$). But the initial four paths also reflect another kind of distinction: whether or not an agency is given deference by the public (or, alternatively, by courts) for handling a high-profile, health related issue (H_r or $\sim H_r$). This distinction reflects, for example, uncertainty about whether a crisis might arise, making food safety more salient, or (conversely) the possibility that the larger public might fail to see firearms issues as matters of health even if it is the CDC that is conducting research on the issue. Although the “health expertise” effect in this model arises initially as a result of an exogenous move by nature, the nature of the effect could be understood to reflect either something about the agency’s overall characteristics (e.g., the public reputation of the CDC at a given point) or about the dynamics of the specific issue an agency is addressing (such as firearms).

Figure 2: Partial Autonomy Game



Although the players know these states of the world differ and would have subjective probability assessments about their likelihood of being in each of

these states of the world, they do not know exactly which of these situations they are in fact facing (until payoffs are earned at the end of the game). After nature's move, the politician decides whether to delegate authority to the agency or not (D or $\sim D$). The agency head then decides on one of three courses of action: attempting to implement a desired policy *without* expending the effort to cultivate a coalition of support between career staff and external civil society groups ($Ch1$), crafting a desired policy but in close coordination with agency career staff and civil society groups ($Ch2$, a more costly but potentially useful approach), or foregoing the opportunity to craft a new policy ($\sim Ch$). If the agency head decides on the last course of action, the game ends (outcomes 1, 2, 3, or 4), with the payoffs reflecting the fact that the agency head has avoided the risk and resources necessary to craft a new policy but has also foregone the benefit of achieving a desired new policy. Otherwise, the agency head's actions are potentially affected either by the external groups alone (if the agency head chooses to avoid cultivating support from employees), or by the employees and then by the external groups. We would assume, of course, that cultivating a coalition of support is costly to the agency — requiring, for example, some combination of side payments, accommodation, or policy compromise that would diminish the agency's payoff (other things being equal). Expending such effort, however, could also increase the agency's ability to withstand external efforts undermining its policy goals.

In this specification, the allocation of payoffs at the end of the game becomes slightly more complex. Quite plausibly, the payoffs are affected by five factors: the *type* of issue an agency is handling, the *decision to delegate* by the politician, the *decision to expend resources on forming a coalition* by the agency head, the *support* of agency employees, and the *response* from outside groups. Even with the added complexity, however, the specification in Figure 2 is straightforward enough to demonstrate how, given a plausible distribution of payoffs, an agency could achieve at least partial autonomy. The agency head, for example, could be emboldened by a high subjective estimate of the probability that the agency will receive deference from the public for handling a sensitive health-related issue such as food safety. Such deference could make the public view political interference with agency initiatives in a harsh light, thus making it costly for the politician to pursue such interference.

The agency head could also bolster the case for agency autonomy by investing resources (e.g., time, energy, or political concessions) to forge a coalition that includes career agency employees. Assume, for instance, that the agency would indeed receive the health-related public deference and the agency's interests were aligned with those of the relevant political coalition. The resulting outcomes would then depend on whether the external group

sought to resist the relevant policy (outcome 24, at the lower right of the figure), or did not resist (outcome 23). Even if the external group threatened to resist, the agency might not be deterred from pursuing a new policy because its payoffs would be affected by “health” deference and by its own efforts to solidify supportive coalitions.

Plainly, this new specification raises a number of questions, such as whether the aforementioned “health expertise” effect might indeed arise, and exactly how agency officials in a modern legal and political context might go about forging coalitions of agency employees, political actors, and external entities. Nonetheless, at least in an advanced industrialized country such as the United States — where pluralist political arrangements coexist with broad reliance on formal laws — one might argue that the second game incorporates some important additional nuances beyond what is described by the conventional principal-agent metaphor. If elements of the preceding specification are at least plausible, then it makes sense to further scrutinize whether particular historical circumstances reflect some of the dynamics that the model illustrates.

To wit: the model implies that public-health agencies may often be far from powerless in the face of external opposition. If private actors are unlikely to passively forego a chance to influence public-health policy, the same is true of agencies. Key to agencies’ ability to influence their context is the fact that agencies are in a complex, evolving relationship with civil society, the private sector, and the more explicitly political components of government such as the elected branches. Civil society organizations representing the victims of foodborne illness, for example, religious organizations, or tobacco control advocates, seek directly to influence the outcomes of public-health policy, as does the private sector. These players, along with the political officials and lawmakers ostensibly overseeing public health agencies and agency career employees, can be allies as well as adversaries from the perspective of agency leaders. As the model suggests, the capacity of public-health agencies to pursue strategies protecting public health arises from the tensions and consequences associated with those relationships and requires an investment of time and resources by agency leaders. Far from being merely the passive objects of political control, agencies use their legal authority to shape their context and, in the process, to alter society by affecting its health and security.

This last point underscores how the second model has certain observable implications. Specifically, it is premised on the idea that a combination of exogenous developments (e.g., moves by nature) and agency choices can result in partial autonomy. Instead of treating autonomy as reflecting complete insulation for expert decision-makers from outside influence, the model implies that autonomy may be affected by agency choices to cement coalitions between the agency’s employees and outside groups. Because some observers might

wonder when or whether these features of the model are reflected in real-world situations, the following cases offer some examples. These cases are worth discussing because they reflect important developments in population health, and they cut across agencies with distinct expertise and jurisdiction. They plainly do not imply that the model fits every instance of public health policymaking. Instead they help advance a more modest but nonetheless important claim — that across multiple issues areas where agencies have implemented significant changes in population health policy, they appear to have experienced a measure of autonomy. The cases also suggest that such partial autonomy arose from a mix of exogenous circumstances and strategic choices, and offer a baseline for considering extensions to the model.

II. TOBACCO: REGULATORY INNOVATION AND LEGISLATIVE CHANGE

The Food and Drug Administration (FDA) has a vast statutory mandate to regulate medical devices, drugs, biologics, cosmetics, and food.²³ Yet for an agency whose mission is often described by lawmakers as protecting “the public health and safety of Americans,” in some respects the regulatory elephant in the jurisdictional room was the agency’s conspicuous failure to regulate the tobacco products that constitute the leading preventable cause of death in the United States.²⁴ This failure arose because of a variety of difficulties faced by regulators — and reflected to some extent in the partial autonomy game depicted in Figure 2.

First, consistent with the uncertainty about moves by “nature” in the partial autonomy game, the agency faced uncertainty about whether courts would determine that there was a legal basis to regulate tobacco under the Food, Drug, and Cosmetic Act (FDCA).²⁵ This challenge was compounded by the previous reluctance of policymakers to assert jurisdiction. The FDA had occasionally considered regulating tobacco products in the long decades since passage of the FDCA. Nonetheless, agency officials had conspicuously declined to do so for its entire history. The FDA’s reluctance persisted over decades despite mounting evidence of tobacco’s severely adverse health effects and a sensible argument that the provisions of the Act provided the agency

23 See PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* 24-25 (3d ed. 2007).

24 For a comprehensive account, see ALLAN M. BRANDT, *THE CIGARETTE CENTURY* (2009).

25 Food, Drug, and Cosmetic Act, 21 U.S.C. § 393 (2010).

residual power to regulate tobacco. Although the FDA had colorable legal arguments that tobacco could be regulated (e.g., as a drug delivery device), such a move would have exposed the agency to certain difficulties. Unlike drugs or medical devices — where the agency’s longstanding goal was to allow only “safe and effective” products to reach the market — cigarettes and other tobacco products could not obviously be rendered safe and effective. Moreover, the vast tobacco industry, though not monolithic, had long waged aggressive efforts — particularly using litigation — against efforts to regulate tobacco.

The agency would also face political risks if it sought to pursue tobacco regulation. In the partial autonomy game, this dynamic is reflected in the agency’s choices following the politician’s decision to delegate authority. In fact, some critics questioned whether the agency had way too much to handle already, even without counting tobacco.²⁶ The FDA and its parent agency (what is today the Department of Health and Human Services, or HHS) had also faced, between the 1960s and 1980s, lawmakers, presidential administrations, and external interests that were divided — to put it charitably — on the advisability of taking on this challenge.²⁷

In addition, regulating tobacco implicated a variety of scientific and policy challenges. During the 1960s, Surgeon General Luther Terry released a report indicating that chemicals in cigarettes were likely to pose serious health risks for smokers. Even after the report, a measure of scientific uncertainty appeared to persist regarding the precise impact of cigarette smoking and tobacco in particular.²⁸ Scientists took decades, for example, to document the impact of secondhand smoke on health or to better understand the addictive properties of nicotine. The lack of credible findings on secondhand smoke and addiction underscored the idea that the problem of tobacco primarily involved individual responsibility, rather than severely time-inconsistent preferences or large negative externalities.²⁹

A turning point in the story was Surgeon General C. Everett Koop’s 1986 report on tobacco.³⁰ More than any other measure to stoke public attention on the issue, Koop’s report galvanized interest with strong claims about the

26 See DAVID KESSLER, *A QUESTION OF INTENT* (2001); Liza Goitein, Gregory S. Chernack, Goodwin Liu & Melvin T. Davis, *Developments in Policy: The FDA’s Tobacco Regulations*, 15 *YALE L. & POL’Y REV.* 399 (1996).

27 See KESSLER, *supra* note 26, at 27-28.

28 See BRANDT, *supra* note 24, at 241-42.

29 See *The Generic Drug Scandal*, *N.Y. TIMES* (Oct. 2, 1989), <http://www.nytimes.com/1989/10/02/opinion/the-generic-drug-scandal.html>.

30 C. EVERETT KOOP, U.S. DEP’T OF HEALTH & HUM. SERV., *SURGEON GENERAL’S REPORT: THE HEALTH EFFECTS OF INVOLUNTARY SMOKING* (1986).

addictive properties of nicotine and the long-term health effects for smokers and nonsmokers affected by secondhand smoke. As Koop publicly reiterated the themes of his now-infamous report, his message increasingly undermined the idea that cigarettes primarily affected those who chose to smoke them. When President George H.W. Bush nominated David Kessler to the FDA Commissioner's Office in the wake of a generic drug scandal, the new FDA Commissioner was expected to address the pharmaceutical regulatory issues that had damaged the agency's reputation.³¹ Yet the Surgeon General's, recent report had already begun galvanizing considerable interest among the public in smoking regulation as a major public health issue — interest shared by employees of the FDA, who convinced Kessler that the agency could play a key role in tobacco regulation.

By the beginning of the following decade, therefore, the FDA's leadership decisively moved the agency towards the goal of regulating tobacco. Under the leadership of Commissioner David Kessler (and with the approval of HHS and the Clinton White House), the FDA began an elaborate effort to assert regulatory jurisdiction over tobacco products. In this effort, Kessler worked to assemble support from a variety of senior career FDA employees (a strategy akin to choosing *Ch2* in the partial autonomy game). Kessler and his staff understood that they were taking on a major battle, one that would be waged within the administration, in Congress, and in the courts.³²

As FDA employees in the agency's Maryland headquarters analyzed tobacco's health properties, the agency's leadership prepared for a fight. Acknowledging that they were facing both legal and political constraints, Kessler adopted a delayed timetable to work with staff in developing an elaborate regulatory rulemaking record documenting the effects of tobacco on health.³³ By 1995, FDA staff were working to chronicle the pharmacological properties of cigarettes and other tobacco products, and the basis for inferring that regulatory interventions would have an impact on market behavior.³⁴

The FDA focused its regulatory strategy not only on changing the entire public's tobacco-related behavior in the very short term, but also on children and youth.³⁵ In 1996, the agency released a wide-ranging tobacco control regulation restricting tobacco advertising, instituting a variety of rules to limit

31 See KESSLER, *supra* note 26, at 9.

32 See *id.* at 9.

33 See *id.* at 167-69.

34 See *id.*

35 See Paul Verkuil, *A Leadership Case Study of Tobacco and Its Regulation*, PUB. TALK: ONLINE J. DISCOURSE LEADERSHIP (1998), <http://www.upenn.edu/pnc/ptverkuil.html>.

the access of minors to tobacco products, and prohibiting the use of marketing tactics such as tobacco company sponsorship of sporting events.³⁶ More specifically, the FDA's proposed regulation limited tobacco companies' ability to advertise close to schools. Tobacco companies would be prohibited from signing marketing deals with athletic events, limiting the companies' ability to connect tobacco products to sports popular with youth. The FDA would oversee implementation of restrictions on access to minors. The significance of any specific regulatory requirement, however, paled in comparison to the fact that the FDA was asserting control over tobacco for the first time in its history.³⁷ Keenly aware of the significance of that historical milestone, Kessler and his allies within the FDA mobilized to garner administration support and ultimately secured the support of President Clinton and Vice President Gore.³⁸

The tobacco companies mounted a severe attack on the legality of the FDA's new regulation. The dispute eventually landed in the Supreme Court.³⁹ Attorneys for the tobacco companies essentially argued that the FDCA's terms did not obviously implicate jurisdiction over tobacco. Nor did the structure of the law, they argued, provide a good fit with tobacco — as these products were not under the proposed FDA rules going to be rendered “safe and effective.” In addition, the tobacco industry argued that congressional practice following the enactment of the FDCA was relevant, wherein Congress had passed several statutes addressing tobacco marketing — thereby indicating that Congress had not (when passing the FDCA) contemplated that it would extend to tobacco. The U.S. executive branch lost in a five-to-four U.S. Supreme Court decision concluding that the FDCA failed to confer on the FDA the authority to regulate tobacco products. Event studies suggest that the litigation appears to have affected the valuation of tobacco companies, underscoring the economic stakes involved in the regulation of tobacco products. When the FDA lost, for example, tobacco companies' valuation increased markedly.⁴⁰

Soon thereafter, the Clinton administration and the FDA supported legislation expanding the FDA's power over tobacco.⁴¹ Meanwhile, tobacco companies were increasingly subject to public scorn because of documents describing

36 See Goitien, Chernack, Liu & Davis, *supra* note 26.

37 See *id.*

38 See Verkuil, *supra* note 35.

39 *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

40 See Jeffrey R. Lax & Mathew D. McCubbins, *Courts, Congress, and Public Policy, Part I: The FDA, the Courts, and the Regulation of Tobacco*, 15 J. CONTEMP. LEGAL ISSUES 163 (2006).

41 See *Clinton Endorses Tobacco Bill*, MARKETWATCH: WALL ST. J. (Mar. 12, 1998), <http://www.marketwatch.com/story/clinton-endorses-tobacco-bill>.

their marketing strategies made public by congressional investigations and state lawsuits. In the months and years that followed, the Supreme Court's decision thus moved the action from the courts to Capitol Hill.

For the next ten years, as much of the tobacco industry sought to squelch tobacco legislation, the FDA remained at the center of efforts to achieve tobacco regulation. Although the Bush administration declined to support legislation to extend FDA jurisdiction to cover tobacco, the agency had already assembled the capacity to provide technical analysis on the issue and at key points provided informal technical assistance to lawmakers on Capitol Hill before advocating for the bill more emphatically during the Obama administration.⁴² In the decade during which success eluded supporters of the bill, the coalition supporting the bill changed and the content of the legislation changed. By the time lawmakers, FDA officials and employees, and civil society groups had taken the time to work through the legislation, the bill expanded in scope beyond the mere codification of the original regulatory rule that the FDA had released in 1996. The legislation now covered the listing of tobacco ingredients and bans on flavored cigarettes, among other matters. In some respects, though, the bill included classic compromises, such as the grandfathering of mentholated cigarettes to get around a ban on flavored cigarettes that would have otherwise applied to mentholated packs as well.⁴³

When the Family Smoking Prevention and Tobacco Control Act was finally signed into law by President Obama in the summer of 2009,⁴⁴ the FDA acquired broad jurisdiction to regulate tobacco products for the promotion of public health. The resulting legislation represented the most significant change in federal public health policy in at least a generation. The Congressional Budget Office estimated that as early as 2019, the bill would result in an eleven percent decline among underage tobacco users, with additional declines among adult

42 See, e.g., Drew Armstrong, *Two-Day Senate Committee Markup Expected for Bill to Regulate Tobacco*, CQ TODAY (May 18, 2009), <http://www.cq.com/doc/news-3119895?wt=RDIYTIRja31SajdNVVI0ZDZxcmp4dw> (discussing FDA Commissioner Hamburg's support for the bill); KESSLER, *supra* note 26 (discussing the capacity the FDA assembled in the late 1990s to develop tobacco regulatory rules and analyze tobacco control policy). For a more general discussion of the FDA's capacity to participate in legislative drafting, see FRAN HAWTHORNE, *INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT* 211 (2005) (describing the work of the FDA's Office of Legislation).

43 See C. STEPHEN READHEAD & VANESSA K. BURROWS, *CONG. RESEARCH SERV.*, R40475, *FDA TOBACCO REGULATION: THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009* (2009).

44 Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, H.R. 1256 (2009).

users over time.⁴⁵ Supporters had forestalled a last effort by supporters of tobacco companies that acknowledged the need for regulation but created a less-powerful agency separate from the FDA to administer limited regulations, one required to publish an annual ranking of the safety of tobacco products. This proposal was defeated when the Tobacco Control Act was enacted. The tobacco episode thus highlights the capacity of the FDA to navigate the risks inherent in pursuing tobacco regulation, and its persistence in that goal even after the Supreme Court ruled against it in the late 1990s.

Moreover, a core premise of the model was that a combination of situational characteristics controlled by nature and agency strategies to forge coalitions could raise the prospects for autonomy. Some observers might point out that legislation ultimately conferring authority over tobacco to the FDA was not opposed by *one* critical private sector actor — the giant Philip Morris tobacco conglomerate.⁴⁶ Nonetheless, the intensity of the opposition from most tobacco companies underscores the extent to which the FDA's moves undermined the interests of most of the tobacco industry, and even Philip Morris initially opposed the FDA's actions. Initially, this tobacco company joined its rivals in seeking to thwart FDA regulation by invoking limits of the then un-amended Food, Drug, and Cosmetic Act.⁴⁷ Only later, after a considerable spike in public attention generated by the FDA's initially failed regulatory effort and tobacco lawsuits of nationwide scope,⁴⁸ did Philip Morris begin cautiously embracing the possibility of legislation providing the FDA with limited authority to regulate tobacco.⁴⁹ The opposition of the rest of the

45 See CONG. BUDGET OFFICE, COST ESTIMATE: H.R. 1256 FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT 6 (2009).

46 See Michael Givel, *Philip Morris' FDA Gambit: Good for Public Health?*, 26 J. PUB. HEALTH POL'Y 450 (2005).

47 See *id.*; see also Laurie Kellman, *Tobacco Bill Hits a Roadblock: Senate Refuses to Vote on It*, CHI. SUN TIMES, June 9, 1998, <http://www.highbeam.com/doc/1P2-4448734.html>.

48 See Andrew L. Roth, Joshua Dunsby & Lisa A. Bero, *Framing Processes in Public Commentary on U.S. Federal Tobacco Control Regulation*, 33 SOC. STUD. SCI. 7, 13 (2003) (discussing how growing concern among the American public over youth access to tobacco provided an important political context for the development of the FDA's proposed regulatory rule regarding youth access to tobacco).

49 See Matthew R. Herington, *Tobacco Regulation in the United States: New Opportunities and Challenges*, 23 HEALTH L. 13, 15 (2010). The Family Smoking Prevention and Tobacco Control Act of 2009, though ultimately acceptable to Philip Morris, in part implemented the 1996 regulatory rule that the FDA had crafted to limit youth access to tobacco products and that Philip Morris had

tobacco industry remained unabated during the entire episode. I return to the issue of divisions within a regulated industry in the case below.

III. FOOD SAFETY: AGENCY-DRIVEN CHANGE IN REGULATORY BARGAINS

The officials who run the U.S. Department of Agriculture (USDA)'s Food Safety Inspection Service (FSIS) face the nearly impossible task of ensuring the safety of the nation's supply of meat and poultry, as well as a number of specific products such as meat-topped pizza and processed egg products.⁵⁰ Together with the FDA, which is responsible for protecting the other eighty percent or so of the food supply, the FSIS constitutes the core of the country's food safety capacity.

In contrast to the FDA, however, the FSIS until recently discharged its role in meat and poultry safety primarily through continuous inspection of carcasses. Federal meat inspection legislation dates from 1890, when lawmakers enacted a statute conferring on the USDA the role of safeguarding that American meat exports met standards for import to the European market.⁵¹ Protecting the food supply by examining carcasses was perhaps a plausible compromise given existing technology and time constraints at that point. Visual carcass examination remained the preferred approach for the agency in 1906, when the Federal Meat Inspection Act was passed.⁵²

By the last quarter of the twentieth century, however, the classic USDA inspection scheme — with carcass-level visual inspection as its lynchpin — was highly problematic. Consumption of poultry products, which are cheaper and have lower fat compared to beef, had increased starkly since the middle of the twentieth century. Whereas processors had slaughtered just under 150,000,000 chickens in the entire year of 1940, by the end of the 1980s the industry was slaughtering roughly 100,000,000 chickens during a single

initially opposed. *See, e.g.*, Brief for Respondents, *FDA v. Brown & Williamson*, 529 U.S. 120 (2000).

50 AM. MEAT INST., *FACT SHEET: MEAT AND POULTRY PRODUCTION & CONSUMPTION: AN OVERVIEW* (2009).

51 The history of the American meat inspection regime is described in *Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems*, 60 Fed. Reg. 6775, 6775 (Feb. 3, 1995) (codified at 9 C.F.R. §§ 308, 310, 318, 320, 325, 326, 327, 381) (Pathogen Reduction).

52 21 U.S.C. § 601 *et seq.* (2010).

week.⁵³ Meat consumption overall also swelled because of the expanding popularity of fast-food restaurants and the growing acceptance of processed and frozen foods using meat ingredients.⁵⁴ Congress and the FSIS worked in tandem between the 1960s and the 1980s to address the situation with several initiatives and legislative reforms. They established a voluntary “Total Quality Control” program giving inspectors access to more of a plant’s production records, as well as an explicit authority for FSIS to calibrate the frequency and thoroughness of inspections of a plant based on its history of sanitation violations.⁵⁵

Even with these changes and a growing staff physically deployed at every meat processing facility operating (as required by the FMIA), USDA inspection methods were increasingly difficult to adapt to faster, higher-volume processing activities. Indeed, the primary mode of regulation presupposed by the statutory framework governing meat and poultry inspection — involving the continuous presence of FSIS inspectors at meat processing establishments — blurred the lines of responsibility between government and industry with respect to limiting safety problems. Beyond the requirement that companies have an inspector continuously present during meat processing, the responsibilities of industry were not always clear.⁵⁶ Even more important, the central food safety concerns involved contamination by microscopic pathogens such as *listeria*, *E. coli* O157:H7, and *salmonella*. The importance of laboratory testing raised further questions about an inspection and processing regime that did not allow products to be routinely held in abeyance while awaiting results. If inspectors suspected contamination but required testing to confirm it, their authority to hold products during laboratory testing was unclear.

Those questions became more prominent during the 1980s and early 1990s, after a series of incidents involving contaminated meat products, particularly involving the aggressive strain of *E. coli* O157:H7. The National Academy of Sciences (NAS) issued a report criticizing USDA’s all but completely constrained capacity to address pathogen-related risks that did not involve obvious sanitation violations.⁵⁷ The highest profile incident was akin to a move

53 See James A. Albert, *A History of Attempts by the Department of Agriculture to Reduce Federal Inspection of Poultry Processing Plants — A Return to the Jungle*, 51 LA. L. REV. 1183, 1184 (1991).

54 See, e.g., Pathogen Reduction, 60 Fed. Reg. 6776-77.

55 See *id.*

56 See *id.* at 6785.

57 Some sanitation problems involved (for instance) the reuse of spoiled pork or meats that had fallen to the shop floor. But the NAS report underscored that the potentially vast problem involving pathogen contamination was largely beyond the purview of existing USDA regulatory rules. See COMM. ON THE SCIENTIFIC

by “nature” in the partial autonomy game opening up a window for a potentially viable policy change involving health. In this case, the triggering event was a high-profile incident involving contaminated meat made available by Jack-in-the-Box restaurants that killed several people and poisoned 500.⁵⁸ Although the Jack-in-the-Box *E. coli* outbreak in California, Idaho, Washington, and Nevada heightened public concern about food safety regulation, such concern did not coalesce around an explicit set of regulatory reforms or statutory changes. Early discussions about possible reforms nonetheless featured some private actors who voiced, at various points in the implementation process, cautious support for changes in meat inspection, joining consumer groups in raising questions about the viability of existing arrangements.⁵⁹

The increasingly poor fit between its prevailing inspection methods and the agency’s articulation of its organizational goals galvanized action among the FSIS leadership and culminated in what has come to be known as the Hazard Analysis and Critical Control Points (HACCP) rule.⁶⁰ The HACCP rule was an elaborate new management-based regulatory regime that placed responsibility on food processors to identify critical control points that could be used to detect and reduce pathogen contamination. Companies would need to develop plans to respond if problems arose and were subject to testing and verification by FSIS. Thus, instead of remaining an organization focused on inspecting meat carcasses, FSIS would increasingly focus on screening and auditing private-sector management plans implementing HACCP.⁶¹

The transition was not an easy one. The Assistant Secretary responsible for FSIS at that point (the mid-1990s) was Michael Taylor. When Taylor asked his staff to set about transforming meat inspection, the agency could deploy broad but not unlimited legal authority, given that the relevant statutes focused almost entirely on physical inspection at meat and poultry processing plants. Taylor had earlier served as a lawyer representing the agricultural company Monsanto.⁶²

BASIS OF THE NATION’S MEAT & POULTRY INSPECTION PROGRAM, NAT’L RESEARCH COUNCIL, MEAT AND POULTRY INSPECTION: THE SCIENTIFIC BASIS OF THE NATION’S PROGRAM (1985).

58 See, e.g., *Bacterial Sickness Hits Dozens of Children*, SEATTLE POST-INTELLIGENCER, Jan. 18, 1993, at B-1.

59 See, e.g., William McAllister, *Recipe for Food Safety Starts from Scratch*, WASH. POST, Feb. 15, 1996, at A25.

60 See Pathogen Reduction, 60 Fed. Reg. 6776.

61 Plans developed by the private sector itself play a prominent role in the HACCP system. But HACCP also incorporated a pathogen testing regime and other features designed to assess the efficacy of industry-generated plans.

62 When Taylor was later named to a new position in the FDA during the Obama administration, some food safety advocates lauded the appointment given his

Perhaps in part to allay consumer groups that were initially concerned about his appointment because of his previous ties to industry, Taylor soon decided to attempt reforms of existing meat and poultry inspection rules. In adapting early twentieth-century statutes to problems of pathogen contamination, the agency deployed novel legal arguments that sought to connect new rules governing private-sector responsibilities for preventing contamination to established statutory and legal concepts such as “adulteration.” The resulting HACCP rule, for example, would eventually seek to treat failure to comply with HACCP requirements (either arising from an unsatisfactory plan for a given establishment or from failure of an establishment to comply with the plan itself) as *de facto* adulteration.

The process yielding this new proposed USDA rule, including the HACCP and pathogen-testing requirements, illustrates both the opposition engendered as well as the varied sources of political support on which the agency drew. As the partial autonomy game emphasizes, the agency faced a mix of opportunities to forge (internal and external) coalitions and risks of opposition. After initially leveraging an early consensus including meat processors and some consumer groups regarding the value of HACCP, USDA officials increasingly encountered controversy over the precise content of the new regulatory rule.⁶³ The most intense controversy focused on whether the new rule should include demanding new standards governing the presence of pathogens in processing facilities. Many meat processors vocally opposed these changes.⁶⁴ Such pathogen standards constituted a considerable break from past practices for USDA, however, given the previously existing approach to meat safety inspection and the nature of the legal provisions governing USDA authority in this area.⁶⁵

knowledge of how the private sector operated and how to constrain excesses there. But civil society groups promoting organic foods criticized it because of their concerns about his work with large private-sector companies that had opposed strict federal regulation. See Gardiner Harris, *New Official Named with Portfolio to Unite Agencies and Improve Food Safety*, N.Y. TIMES, Jan. 14, 2010, http://www.nytimes.com/2010/01/14/health/policy/14fda.html?_r=0.

63 See HACCP “Mega Reg.” *Withdrawal Urged by Meat and Poultry Groups*, FOOD CHEMICAL NEWS, Aug. 28, 1995, 1995 WL 8215906.

64 See, e.g., *Industry Criticized by SFC for Efforts to Delay, Kill USDA HACCP*, FOOD CHEMICAL NEWS, June 5, 1995, 1995 WL 821543.

65 Although that authority did provide, in USDA’s analysis, sufficient legal justification for instituting the new pathogen testing regime, there is little doubt that the agency would have designed the system differently if it had been writing a new statute. See Denis R. Johnson & Jolyda O. Swaim, *The Food Safety and*

The controversy over the new pathogen testing requirements delayed implementation of the new regulatory rule for a considerable period. Even several years after the Jack-in-the-Box imbroglio that had galvanized public attention, USDA was still working on finalizing the new provisions. From the perspective of USDA's officials, regular testing for the presence of *E. coli* and *salmonella* pathogens would play a critical role in validating the extent to which industry establishments were successfully carrying out their responsibilities under an HACCP regime. In particular, USDA officials determined that achieving an adequate degree of safety in meat and poultry processing warranted a regime linking the new HACCP requirements to testing for *E. coli* and *salmonella*. To adapt the testing regime to the existing statute, USDA declared these pathogens "adulterants" — a finding that allowed the agency to use the full extent of its statutory powers against these contaminants.⁶⁶ Although some consumer groups supported the more expansive approach USDA sought to take, the agency encountered swelling opposition from industry representatives eager to avoid a scenario subjecting their operations to strict pathogen standards.⁶⁷ As expectations built among the public and civil society groups that USDA would finally issue the new regulatory rule bundling HACCP with the new pathogen standards, some lawmakers from the House Agriculture Committee supportive of the meat processing industry sought to force the agency into a compromise with industry.⁶⁸

Just as FSIS was racing to finalize the new rule, the USDA faced a leadership transition. Secretary Michael Espy had already departed, and incoming Secretary-Designate Dan Glickman had yet to be confirmed. The leadership of FSIS within USDA sought support from Glickman, however, and he signaled a willingness to back the agency's strategy of issuing a new rule with stringent requirements for pathogen testing. So did the White House, where the staff of Vice President Gore among others had begun to follow the developments at USDA. By the time the new HACCP rule was ready,

Inspection Service's Lack of Statutory Authority to Suspend Inspection for Failure to Comply with HACCP Regulations, 1 J. FOOD L. & POL'Y 337 (2005).

- 66 See *Supreme Beef Processors v. U.S. Dep't of Agric.*, 275 F.3d 432 (5th Cir. 2001). The term "adulterated" is used when the agency finds that contamination arose because of the presence of an "adulterant." 21 U.S.C. § 601(m)(1) (2010) (an "adulterant . . . bears or contains any poisonous or deleterious substance which may render it injurious to health").
- 67 See *Small Processors Protest Inequities, Costs of HACCP Plan*, FOOD CHEMICAL NEWS, June 5, 1995, 1995 WL 8215441.
- 68 See, e.g., Dion Casey, *Agency Capture: The USDA's Struggle to Pass Food Safety Regulations*, 7 KAN. J.L. & PUB. POL'Y 142 (1998); Robert Greene, *Compromise Reached on Meat Rules*, TACOMA TRIBUNE, July 19, 1995, at A3.

President Clinton announced it at the White House and claimed credit for a package of reforms that the agency had crafted over several years. The new rule appealed to the Clinton administration despite the opposition of some lawmakers and industry representatives.⁶⁹

USDA faced a variety of legal hurdles in implementing the regulatory approach built into the new rule, showcasing how the prospect of opposition from external groups incorporated into the partial autonomy game could result in litigation. For example, one legal challenge insisted that the agency's preliminary determination that *E. coli* O157:H7 was an adulterant, which the agency had initially announced informally before the 1996 promulgation of the new regulatory rule, needed to follow a more formal regulatory process.⁷⁰ USDA prevailed by arguing that some aspects of its new approach were essentially changes in its enforcement strategy, and did not require compliance with the requirements for a new regulatory rule. In dealing with *salmonella*-contaminated meat, USDA relied on a blunt feature of the early twentieth-century statutory scheme: no establishment could take to market meat and poultry products from an operation that did not have USDA inspectors present.⁷¹ Removing the inspectors would thus force the establishment to suspend operations. Because USDA lawyers explicitly linked the removal of inspectors to HACCP violations, the agency became increasingly vulnerable to the charge that the statutory authority for inspections did not allow them to be removed as a means of enforcing a regulation such as the HACCP rule.⁷² Undaunted by the legal challenges to its preferred enforcement strategy, USDA has turned to its more explicit statutory authority to drastically ramp up testing for *E. coli* O157:H7 and conduct more intrusive and costly inspections if HACCP problems emerge.⁷³

Proponents of capture might contend that HACCP was a largely symbolic response, with few long-term consequences for industry or the public. History suggests otherwise. HACCP soon received a measure of attention from scholars and policymakers because of its focus on management and performance standards.⁷⁴ The evolution of foodborne illness patterns since HACCP was instituted suggests that, consistent with USDA's theoretical analysis and

69 See *HACCP Negotiated Rulemaking Amendment Withdrawn in Compromise*, FOOD CHEMICAL NEWS, July 24, 1995, 1995 WL 821585.

70 See Casey, *supra* note 68, at 159 n.140.

71 See Pathogen Reduction, 60 Fed. Reg. 6776-77.

72 *Supreme Beef*, 275 F.3d 432.

73 See *Munsell v. Dep't of Agric.*, 509 F.3d 572 (D.C. Cir. 2007).

74 See, e.g., Cary Coglianese & David Lazer, *Management-Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 LAW & SOC'Y REV. 691 (2003).

contemporaneous cost-benefit analyses, the rule has had a material effect on foodborne pathogens. In a two-year period following implementation of the rule, for example, the prevalence of *salmonella* in all classes of raw meat products regulated by FSIS declined substantially and fell by as much as fifty percent in young chickens.⁷⁵ Subsequent research on *salmonella* infection rates among the U.S. elderly indicates that the HACCP rule contributed to decreasing rates of infection.⁷⁶ In 2011, a meta-analysis of pathogen contamination in slaughterhouses before and after HACCP supports the conclusion that the reforms reduced bacterial counts.⁷⁷ In succeeding years, the FDA implemented HACCP procedures similar to those implemented by USDA for products such as seafood and fruit juices.⁷⁸

More broadly, the case of HACCP for meat and poultry bears some similarities and differences to the tobacco case. The FDA's efforts to regulate tobacco took far longer to come to fruition, and did not involve a discrete, pitched crisis to galvanize interest. As the model suggests, some aspects of the situations that can heighten the prospects for this type of agency initiative depend on exogenous moves by nature. The outbreak of health problems arising from the contaminated beef linked to Jack-in-the-Box catalyzed public concern about food safety, making regulatory changes more likely.⁷⁹ Not surprisingly, the industry responded by embracing in principle the idea of new process controls to be implemented by food processors themselves,⁸⁰

75 U.S. DEP'T OF AGRIC., FOOD SAFETY & INSPECTION SERV., PROGRESS REPORT ON SALMONELLA TESTING OF RAW MEAT AND POULTRY PRODUCTS, 1998-2000 (2000).

76 Kenneth K.H. Chui et al., *Geographic Variations and Temporal Trends of Salmonella-Associated Hospitalization in the U.S. Elderly 1991-2004*, 9 BMC PUB. HEALTH 447 (2009).

77 See Barbara Wilhelm et al., *The Effect of Hazard Analysis Critical Control Point Programs on Microbial Contamination of Carcasses in Abattoirs: A Systematic Review of Published Data*, 8 *FOODBORNE PATHOGENS & DISEASE* 949 (2011). Estimating the precise effect size of policy change is difficult in this context without random assignment, but the result of this analysis and multiple additional studies in the decade and a half after HACCP was implemented are consistent with the arguments USDA advanced.

78 See *New Rules Aim for Cleaner, Safer Seafood*, NEW ORLEANS TIMES-PICAYUNE, Dec. 6, 1995, at A1.

79 Cf. Mariano-Florentino Cuéllar, "Securing" the Nation: Law, Politics, and Organization at the Federal Security Agency, 1939-1953, 76 U. CHI. L. REV. 587, 651 (2009) (discussing the impact of exogenous shocks on policymaking and government organization).

80 See *supra* note 62 (discussing early industry support for some regulatory changes following the Jack-in-the-Box controversy).

particularly if (as expected) those new standards reflected a philosophy of harnessing industry knowledge rather than imposing conventional command-and-control measures.⁸¹

As with the tobacco case, however, the USDA proposal faced pitched opposition from industry. While it is telling that external interests sometimes accept or even welcome regulatory action,⁸² these examples both what certain private actors resisted and what they embraced. By and large, the meat industry representatives who had once supported the concept of HACCP parted company with USDA when the agency embraced relatively strict pathogen testing in addition to the overall framework for regulatory flexibility contained in the new 1996 regulatory rule.⁸³ The fierce litigation that ensued over *salmonella* standards in particular reflected deep-seated private resistance to the details of what USDA sought to achieve and highlight an important methodological limitation in capture-oriented accounts. Those accounts sometimes selectively emphasize the initial support in the industry, such as private actors' enthusiasm for HACCP requirements following the Jack-in-the-Box contamination incident. The HACCP story thus illustrates initial broad acceptance in the private sector for a general regulatory strategy that later produced considerable conflict.

In both the tobacco case and the meat and poultry inspection scenario, however, a common theme is directly reflected in the structure of the partial autonomy game: the prospect of strong resistance from many elements of the relevant industries seeking to stymie regulatory efforts. What acceptance from private actors emerged, moreover, did so against a backdrop of broad public concern and capacity for agency action. Had the agencies been too weak to present a credible threat of regulation and enforcement, the resulting pluralist bargain over regulatory policy would have almost certainly been quite different. These characteristics of the tobacco and food safety stories described here underscore the risks of inferring capture simply from the presence of some private-sector acceptance of regulatory measures.

The changes in meat and poultry safety also highlight the difficulty of simply relying on the language of conventional principal-agent models to understand certain cases of public health policymaking. A simple principal-agent account of the USDA HACCP rule might focus on the idea that policymakers simply granted discretion to the agency by giving it sufficient legal authority to make new rules. Though broad delegations can conceivably play a role in public-health innovation, many conventional principal-agent models describing the

81 Cf. Coglianese & Lazer, *supra* note 74.

82 For such a perspective, see *id.*

83 See RICHARD KLUGER, *ASHES TO ASHES: AMERICA'S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS* (1996).

agency as the “agent” of its political superiors seem to capture few of the relevant nuances. One must further distinguish between *discretion* — a central feature of many principal agents and akin, for example, to how an agency such as USDA exercises authority under a preexisting regulatory regime — from the kind of *partial autonomy* described in the model presented in Section I.C.

The latter better describes the changes USDA undertook when implementing HACCP.⁸⁴ Although discretion implicates the authority that an organization receives under explicitly recognized institutional rules, autonomy refers to the organization’s ability to influence its broader context. Sometimes formal models or narrative descriptions of agency relationships focus on how a principal might optimally allocate discretion to an agent. Such depictions risk neglecting the capacity of a public organization, under certain circumstances, to fundamentally reshape its relationship to its “principal,” or the risks to the principal (or, for that matter, an external interested party) from interfering with agency decisions. Whether because of some exogenous factor that makes health-related functions riskier to control or because of the formation of coalitions that enhance the agency’s reputation, the agency’s position can evolve in a manner that neither the organization nor the “principal” initially anticipated.

IV. AGENCY CAPACITY AND PUBLIC HEALTH SURVEILLANCE

Some of the epidemiological analyses informing public-policy debates about tobacco and food safety come from researchers at the Centers for Disease Control and Prevention (CDC), a once-small malaria control agency that has since grown into a sprawling organization capable of monitoring public health developments in far-flung corners of the world.⁸⁵ This Part briefly describes how the CDC also reflects a degree of autonomy as it has come to play an important but underappreciated role in shaping public-health responses — including some with quasi-regulatory implications for powerful economic actions. Not only does the CDC’s recent history appear to reflect a measure of autonomy, but it also reflects an important feature of the model depicted in Section I.C. — the importance of an agency’s reputation as an apolitical, technical expert on health policy. The CDC appears to have leveraged its initial reputation through extensive efforts on the part of agency officials to build

84 See, e.g., CARPENTER, *supra* note 4 (discussing distinctions between autonomy and discretion).

85 See ELIZABETH W. ETHERIDGE, *SENTINEL FOR HEALTH: A HISTORY OF THE CENTERS FOR DISEASE CONTROL* 155 (1992).

a cohesive staff and avoid political entanglements, even if it is occasionally constrained by public controversy or disagreements with other agencies.

The CDC is best known as an agency that reports health information and helps governments respond to disease outbreaks. Yet the CDC also has an important, if underappreciated, regulatory role. First, Congress has vested the CDC with the capacity to regulate in areas such as disease surveillance and quarantine.⁸⁶ Although the agency rarely uses such authority, its residual capacity to do so (and the sweeping nature of some of its authority) makes the CDC an important player in regulatory policy. Second, the CDC is the quintessential example of a networked agency, whose judgments are amplified through an elaborate web of formal and *de facto* relationships with other agencies whose operational or regulatory decisions (in areas ranging from biosecurity to occupational safety) turn heavily or exclusively on CDC determinations.⁸⁷ In a similar fashion, CDC's decision to release information or issue a warning can directly influence market behavior and shape the litigation environment.

As the CDC evolved, it developed three features affecting its place in the American regulatory state. First, the agency's legal authority gave it the necessary power to gather health-related information and, increasingly, to make policy-relevant recommendations capable of exerting a powerful effect on private industry.⁸⁸ Such authority could enhance the agency's influence and bargaining position relative to other public organizations lacking the capacity to gather such data. Second, the agency's practical capacity to gather and analyze information changed over time, as new staff joined the agency and its relations with state health authorities grew closer.⁸⁹ Through early exchanges of information and relationships playing out largely outside public view, state agency reporting practices evolved partly in response to CDC specifications, and the CDC in turn perfected reporting mechanisms such as FoodNet to interact with state health agencies.⁹⁰ Third, armed with data and analytical

86 See generally Lawrence O. Gostin, *Federal Executive Power and Communicable Disease Control: CDC Quarantine Regulations*, 36 HASTINGS CTR. REP. 10 (2006).

87 See, e.g., ETHERIDGE, *supra* note 85.

88 See generally SARAH A. LISTER, CONG. RESEARCH SERV., RL31719, AN OVERVIEW OF THE U.S. PUBLIC HEALTH SYSTEM IN THE CONTEXT OF EMERGENCY PREPAREDNESS (2005).

89 See ETHERIDGE, *supra* note 85, at 16.

90 See CTRS. FOR DISEASE CONTROL & PREVENTION, PUBLIC HEALTH PREPAREDNESS: MOBILIZING STATE BY STATE, A CDC REPORT ON THE PUBLIC HEALTH EMERGENCY PREPAREDNESS COOPERATIVE AGREEMENT (2008); PRINCIPLES OF PUBLIC HEALTH PRACTICE 86 (F. Douglas Scutchfield & C. William Keck eds., 2d ed. 2003) ("Among all federal health agencies, the CDC is undoubtedly the one most

capacity, the CDC began to occasionally garner public attention — resulting in both challenges and opportunities for the agency. Although controversy occasionally arose over CDC recommendations, most notably involving the swine flu outbreak in the late 1970s,⁹¹ the agency's role generally bolstered a favorable reputation for technical competence.⁹² The agency's reputation, in turn, enhanced its ability to shape social behavior and to further affect other agencies through its recommendations.

The potential for the CDC to affect private economic interests is readily apparent in developments involving Reye's syndrome and warnings regarding aspirin beginning in the late 1970s. At the time, the CDC began to investigate the possibility that children with smallpox or other infectious diseases could be at risk for Reye's syndrome if they consumed aspirin or related products.⁹³ The consequences could include mild but long-term brain damage. The CDC researched the issue intensely and, even in the absence of complete confidence, concluded that it was appropriate to publish research indicating the basis for its concern. Initially, the FDA agreed to a joint statement about the risks of aspirin for kids because of Reye's syndrome.⁹⁴ Then the aspirin industry objected and pleaded for more time. The CDC published its study despite such pressure. Although the White House reportedly interfered eventually, U.S. Department of Health and Human Services (HHS) political appointees apparently sided with the CDC. Nonetheless, the CDC launched a second study before warning labels were changed on aspirin. The conclusions of the second study were compelling, and warning labels were eventually added. Throughout this episode, the CDC resisted pressure from aspirin manufacturers to slow down. Moreover, the CDC was arguably in a precarious position following controversy over what was then perceived as an overreaction to

heavily invested in intergovernmental relationships with state and local public health organizations.”).

91 See generally RICHARD E. NEUSTADT & HARVEY V. FEINBERG, *THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY DISEASE* (1978) (discussing the impact of perceived CDC overreaction to the 1976 swine flu outbreak and subsequent consequences for the agency's capacity to shape policy).

92 See ETHERIDGE, *supra* note 85, at 122.

93 See *id.* at 296 (discussing Reye's Syndrome and the CDC role); Betty Anne Williams, *Administration Accused of Sidetracking Aspirin Campaign*, ASSOCIATED PRESS, Nov. 29, 1983, <http://www.lexisnexis.com.ezproxy.stanford.edu/lncui2api/api/version1/getDocCui?lni=3SJ4-KFM0-0011-53C2&csi=304478&hl=t&hv=t&hnsd=f&hns=t&hgn=t&oc=00240&perma=true> (by subscription).

94 Stephen B. Soumerai, Dennis Ross-Degnan & Jessica Spira Kahn, *Effects of Professional and Media Warnings About the Association Between Aspirin Use in Children and Reye's Syndrome*, 70 MILBANK Q. 155 (1992).

swine flu in the 1970s. The CDC's experience with Reye's syndrome, in short, shows how the agency was entirely capable of disagreeing with the FDA and affecting the priorities of its parent cabinet agency. But there were also limits to the CDC's influence, given both the jurisdiction of the FDA and the agency's reluctance to pursue a pitched interagency battle when its public reputation was at low ebb.

A somewhat similar dynamic — reflecting a relatively robust CDC role tempered by some external constraints — ensued as the CDC exercised surveillance and prevention functions associated with lead poisoning. Working with other federal agencies, the CDC played a leading role in sounding the alarm about lead poisoning. As it concluded further study of the health effects of lead exposure from the 1960s through 1970s, the CDC gradually lowered advisable levels of lead exposure.⁹⁵ During the 1970s, the CDC played the leading role in organizing broad lead-screening efforts. These moves inspired aggressive detractors, including in some cases local municipalities and insurers. More recently, however, the CDC abandoned its goal of universal childhood lead screening. Reports of attempted political interference with a CDC lead-related advisory committee in the last decade underscore the continuing political stakes involved in CDC determinations involving lead-related issues.

As with the hypothetical agency seeking autonomy in the models discussed earlier, CDC officials do not always succeed in achieving their goals. The limits to the power of what is perhaps the world's most sophisticated health surveillance agency, however, also illustrate two important points connecting the CDC to broader discussions of agency autonomy and public-health policy. First, the agency's health surveillance capacity required a measure of autonomy to build and operate in its current form. Otherwise, the agency's ability to disagree with the FDA or industry would be constrained. That partial autonomy appears to have evolved in no small measure through a combination of public reactions supportive of the CDC's reputation in addressing risks such as biological warfare,⁹⁶ and the actions of CDC officials who recruited a highly technical staff and forged a cohesive culture within the organization.⁹⁷ Second, the agency's health surveillance capacity shapes outcomes, and therefore its

95 See Barbara Bernay, *Round and Round It Goes: The Epidemiology of Childhood Lead Poisoning, 1950-1990*, 71 *MILBANK Q.* 3, 10 (1993) (discussing the epidemiology and scope of the problem involving childhood lead poisoning); Gerald Markowitz & David Rosner, *Politicizing Science: The Case of the Bush Administration's Influence on the Lead Advisory Panel at the Centers for Disease Control*, 24 *J. PUB. HEALTH POL'Y* 105 (2003).

96 See ETHERIDGE, *supra* note 85, at 38-39; 47-48.

97 *Id.* at 43.

operation has high economic and political stakes. Although other agencies sometimes reject CDC recommendations, external actors have often played important roles in bolstering the agency's reputation and capacity. Political appointees citing CDC data, and international actors such as the World Health Organization, depend on the agency and describe it as a neutral, technical decision-maker.⁹⁸

Given these factors, it is a telling irony that the agency's health surveillance mission, at least outside the context of research on firearms,⁹⁹ can appear to a variety of constituencies to be almost entirely apolitical. Recall that the model depicted in Figure 2 includes two branches at the outset where nature allows the agency to convince the public that the bulk of its mission involves highly technical or scientific health-related activities. All the play that follows in each of those two scenarios is affected by the agency's reputation with the public. In the discussion of the FDA's work developing tobacco regulations, I observed how agencies — consistent with the model — could bolster or protect their reputation if agency leaders created alliances with career appointees who could otherwise undermine the agency.

The CDC's recent experience suggests a different dynamic that could affect agency reputation — one that could be addressed in a simple extension to the model. If the CDC, for example, insisted on pursuing an agenda that lawmakers and their constituents viewed as involving a cultural issue, such as firearms, then the agency's reputational advantages could erode. As a description of the agency's capacity to forge technical competence and resist routine partisan political interference in certain states of the world, then, the term "apolitical" may be apt. Where the description is less apt is in how it implicitly plays down the political-economic consequences of robust state capacity to monitor health-related developments.

We can come full circle by discerning those consequences in the domains of food safety and tobacco regulation, where public-sector officials with legal authority to monitor population health and a reputation for competence played important roles in creating the base of technical knowledge that facilitated the implementation of HACCP in the food safety domain and, eventually, the

98 See, e.g., Andrew Fies, *Does Politics Influence the CDC?*, ABC NEWS (June 1, 2007), <http://abcnews.go.com/Health/Politics/story?id=3235565> (citing a 2005 survey indicating that the CDC is among the government's most trusted institutions).

99 The CDC has faced constraints in studying firearms violence. See, e.g., Brad Plummer, *Here Are the Questions the CDC Would Study — If It Could*, WASH. POST, June 8, 2013, <http://www.washingtonpost.com/blogs/wonkblog/wp/2013/06/08/here-are-the-questions-about-gun-violence-the-cdc-would-study-if-it-could/>.

regulation of tobacco products.¹⁰⁰ Even when other agencies wielded the specific authorities to regulate tobacco or change food safety requirements, the CDC provided data to support regulatory action. Over decades, it gathered, analyzed, and released to the public health information that spurred the other agencies to action. As doctors and public-health analysts generated and analyzed data with potentially stark consequences for lawmaking and regulation, then, it was among their most profound and underappreciated political achievements to foment the narrative that their role was essentially apolitical.

Perhaps in part because of the technical uncertainty and perceptions regarding scientific expertise confronting lawmakers, the CDC and other public-health agencies often benefit from relatively supple legal authority. In a system where statutory change is difficult and plausible arguments about existing legal authority are one coin of the realm, a more flexible statute is worth its weight in gold. Even when agencies ultimately fail at convincing the courts, as did the FDA in pursuing tobacco regulation, their broad authority can give them crucial space to engineer the policy in question. Broad jurisdiction cutting across different issues also helps validate the agencies' preparatory work by giving them a track record across different problems. By deploying analogies and arguments about the complementarity between existing and new efforts to cover tobacco or food safety, agencies may bolster their reputations. Given the specificity of their substantive statutes, agencies such as the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) or the Internal Revenue Service (IRS) wield limited authority by comparison, or in some cases possess jurisdiction honeycombed with appropriations restrictions blocking even the gathering of information necessary to develop persuasive legal or policy arguments.¹⁰¹ The result is a mismatch between the scope of certain agencies' legal jurisdiction and their far narrower capacity to address policy problems in a meaningful way — incongruity almost certainly sufficient to dilute an

100 For one example of the CDC's continuing role in shaping tobacco policy, see CTRS. FOR DISEASE CONTROL & PREVENTION, NAT'L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION TOBACCO USE: TARGETING THE NATION'S LEADING KILLER: AT A GLANCE 2010 (2010), available at http://www.cdc.gov/chronicdisease/resources/publications/aag/pdf/2010/tobacco_2010.pdf. The CDC's prominent role in food safety is discussed in, among other sources, *Selected Federal Agencies with a Role in Food Safety*, FOODSAFETY.COM, <http://www.foodsafety.gov/about/federal/index.html> (last visited Oct. 28, 2013).

101 See, e.g., WILLIAM J. VIZZARD, SHOTS IN THE DARK: THE POLITICS, POLICY, AND SYMBOLISM OF GUN CONTROL (2000); Edward D. Kleinbard, *The Congress Within the Congress: How Tax Expenditures Distort Our Budget and Our Political Process*, 36 OHIO N.U. L. REV. 1 (2010).

agency's reputation for competence even among constituencies supportive of its mission.

CONCLUSION

Virtually all legal arrangements are implemented by organizations. Consequently, developments in population-based health depend heavily and in underappreciated ways on how agencies respond to their constraints and opportunities. As agencies respond, plausible theoretical assumptions suggest that agencies are not necessarily captured by private interests. They can forge coalitions between internal and external constituencies to affect their position in society (including, for example, their formal legal authority, their reputation, and the costs to politicians of interfering with them). Partially autonomous agencies can also work in concert with lawmakers and political officials, even as they influence the elected branches.

This Article offered a simple framework for modeling the prospects for partial autonomy of public health agencies. It then investigated how certain American public health agencies have been able, at least in some cases, to use their partial autonomy to develop significant health-policy innovations. While the dynamics of agency policymaking and implementation are complicated and often *sui generis*, these episodes highlight some of the implications that emerged in the earlier theoretical discussion of partial autonomy. Consistent with the theory presented in Part I, agencies appear to have avoided capture by private interests and achieved a degree of autonomy in the development of public health policies. Moreover, the process through which agencies forged a measure of independence reflects key features of the partial autonomy game, such as the importance of exogenous shocks and the strategic decisions of agency leaders to expend resources (in terms of time, energy and political capital) forging coalitions inside and outside their agencies. Agency leaders leveraged relationships with career staff, and sought to bolster reputations for technical expertise arising from their health-related jurisdiction. Moreover, rather than encountering external interests with virtually unlimited power to constrain agency action, officials instead often confront external actors that are constrained in some fashion. In the tobacco and food safety cases, for instance, agency efforts to engage in regulatory innovation benefited from fragmentation among relevant private-sector actors.

Using these techniques, agencies have pursued both regulatory efforts as well as health-related surveillance activities with quasi-regulatory consequences by leveraging a mix of legal authority, agency capacity, and supportive external coalitions. Through a combination of internal policy innovation, legal argument,

and alliances with external political players and public constituencies, agencies have successfully changed the way millions of Americans get their food. Public officials have forged a new regulatory context for tobacco, contributing to changing social norms regarding the use of products that kill nearly half a million Americans a year. They have changed public-health standards governing lead and medical practices concerning the use of a popular drug such as aspirin.

Instead of reflecting a conventional principal-agent scenario, wherein legislative principals specify goals that public bureaus implement acting as “agents,” agencies responsible for public health often reflect a blurring in the roles of principal and agent. Although health agencies do not always succeed in getting their way,¹⁰² elected leaders and cabinet secretaries routinely defer to health agencies even when those agencies lack the legal authority to have the final say. Agencies often remain partially constrained nonetheless. The political economy of legal and policy change plainly implicates lawmakers often (if not exclusively) concerned about reelection, executive branch officials making stark political tradeoffs across issues, and a disaggregated public of people who rarely understand the stakes involved in complicated regulatory decisions to manage risk. In that environment, private actors forge coalitions, cultivate reputations, and deploy legal arguments to advance their agendas. Public health agencies play in the same space. As long as public health is understood to depend on something more than merely voluntary action or common law doctrines, then building a healthier society depends on agencies’ hard-fought efforts to resist capture, forge partial autonomy, and innovate with scarce resources and legal authority.

102 For a discussion of how the FDA’s initial decision to permit over-the-counter access to an emergency contraceptive was rejected by political appointees at the Department of Health and Human Services, see *Tummino v. Hamburg*, 936 F. Supp. 2d 162 (E.D.N.Y. 2013).

