

**“Regulation of Food Quality:
Deep Capture and Economies of Scope between Innovation and Influence”***

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Abstract

In this paper, existing work on credence goods is extended to include a "diagnosis" stage whereby ill-informed consumers rely on a third party to certify that food products have beneficial characteristics. This compares to existing models of credence goods which focus only on a "treatment" stage, i.e., food is simply certified as having such characteristics. Adding the diagnosis stage allows for "deep capture" by food producers who attempt to influence regulatory outcomes on what quality claims can be made about food products: specifically an innovator, the “expert”, can expend resources to “nudge” regulatory assessment of quality samples in a positive direction, assuming also that there are economies of scope between innovation and influence.

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1. Introduction

As pointed out originally by Darby and Karni (1973) and discussed at length in Dulleck and Kerschbamer (2006), there is considerable potential for fraud where “experts” have an incentive to exploit informational asymmetries at both “diagnosis” and “treatment” stages in markets for credence goods. The canonical example of this is an expert, a doctor (car mechanic), diagnosing a medical (mechanical) problem and providing treatment (repairs). The problem facing the consumer is that they have insufficient information to judge whether the diagnosis is actually correct and also whether they have actually received the appropriate level of treatment. In other words, experts know more about the type of good that a consumer needs (diagnosis), and may exploit that informational asymmetry by defrauding the consumer in terms of the quality of the good actually provided (treatment).

There has been extensive analysis by agricultural economists of credence goods, e.g., Segerson (1999), Roe and Sheldon (2007), and Bonroy and Constantatos (2015). However, analysis has focused on the treatment stage only and how policy instruments such as third-party-certification and labeling may be used to ensure consumers are not cheated on claimed food product quality. In other words, the credence good problem is interpreted to mean consumers are unable to verify quality both before and after consumption, all the time ignoring the possibility that firms may defraud consumers because the latter have insufficient information to judge whether they needed the claimed quality in the first place.

It is often the case though, that the diagnosis stage for food products occurs at, the level of the regulator and not the consumer. Specifically, in many developed countries, food products that are considered novel due to the product itself, an ingredient, or the food production process, and which may present a danger to consumers, are evaluated by a regulatory agency prior to their commercial release. Obviously if the regulator has perfect information about a novel food that it is presented for evaluation, and also acts in the best interests of the consumer, the diagnosis stage

is straightforward, i.e., only safe novel foods will be permitted to be commercially released, the credence good problem collapsing to the treatment stage. Two things militate against this outcome: first, the complexity and extent of innovations means that firms seeking approval for their novel foods will necessarily be experts at the diagnosis stage; and second, whether or not the regulator is well-informed about novel foods, there is always the possibility that they will be subject to regulatory capture in the approval process. Importantly, if there are economies of scope between the extent of innovation by firms and the degree of influence they can exert over the regulator, there is clear potential for what has been termed “deep” capture of the regulator as distinct from “shallow” capture (Hanson and Yosifon, 2003).

In this context, the focus of this paper is on setting out a framework for examining the regulatory process for novel foods where both shallow and deep capture of the regulatory body can occur. The structure of the paper is as follows: first, the concepts of shallow and deep capture are set in the context of the orthodox literature on regulatory capture; second, the basic regulatory and influence structure, and the firm-regulator timeline are introduced; third, a candidate model for thinking about voting behavior in regulatory advisory committees is sketched out; and, finally the paper is summarized, along with a brief discussion of some policy implications that can be drawn from the analysis.

2. Regulatory Capture

2.1. Orthodox Approach

Prior to the seminal contribution of Stigler (1971), the presumption of “public interest” theory of economic regulation was that a benevolent social planner would behave as a rational actor, their preferences for regulatory outcomes and other economic policy choices being consistent with the public interest. Stigler’s contribution drew from his observation that firms may have an incentive to seek regulation, and that politicians are willing to supply that regulation if it allows them to maintain or augment their power. This basic idea was subsequently refined by Peltzman (1976) in the context of a politician(s) determining the extent to which they will allow an

industry to set prices above the competitive level. Peltzman's model assumes three types of player: politicians who want to maximize their majority, which is a function of the payoffs of the other two players, the price paid by consumers and the profits of firms. The basic idea here is that, depending on whether the initial market structure of the industry is one of natural monopoly or is competitive, the politician will lower (raise) price in order to gain the votes of consumers (firms) up to the point where the marginal benefit of doing so (votes gained) is outweighed by the marginal cost (votes lost).

A problem with the above approaches, known collectively as the Chicago school, is that they apply broadly to a class of political economy problems involving rent-seeking, and are not very specific to the notion of regulatory capture. In addition, as Laffont and Tirole (1993) note, the approaches have two key methodological limitations: first, because they ignore informational asymmetries, regulated firms are unable to extract rents, and therefore have no incentive to try to influence regulators, i.e., there is no agency problem; second, the supply side of policies is a "black-box", ignoring the agency relationship between the government and appointed regulator.

Bó (2006) in his review of the literature shows that introducing an explicit regulatory body in a principal-agent setting allows for the idea that a political principal wants to deal with the possibility that an agent, the firm, may have an incentive to capture the regulator. Bó describes a model with two key components: first, a natural monopoly has private information about its cost of production, so that the government is uncertain about the price the firm should be allowed to charge consumers. Due to the fact that consumers value output by the firm, and there is a positive probability that production costs really are high, it is possible that the contract offered to the firm will allow them to capture rents when production costs are actually low. Second, because of the information asymmetry, the government will appoint a regulator (supervisor) whose function is to specialize in learning as much as possible about the true production costs of the firm. The problem facing the principal, (government), is that the agent (the firm) has an incentive to "bribe" the regulator (supervisor) into not revealing when their costs of production

are low, the amount of the bribe being just equal to the value of the informational rent. Of course actual bribes are typically illegal, but they do not have to be explicit for regulatory capture to occur: the concept of “revolving doors” can be appealed to here, whereby regulators may bias their decisions in order to enhance their chances of future employment in the very industry they are regulating, i.e., the public concern is that there may be a conflict of interest on the part of the regulator (Che, 1995).

This setting appears a logical way of approaching the issue at hand: what are the implications of a firm in the food industry (the expert) seeking approval of a novel food (diagnosis) from a regulatory body such as the US Food and Drug Administration (FDA)? The firm knows more than the regulator, and, therefore, has the incentive to extract rents through capture of the regulatory agency. In particular, financial ties between members of FDA advisory committees, and the firm(s) seeking approval, may bias the recommendations of such committee members in favor of approval of a novel food, even if they have information/concerns about the potential for the novel product to be unsafe. Concern about conflicts of interests involving members of FDA advisory committees became particularly intense after the pharmaceutical firm Merck withdrew its painkiller Vioxx in 2004 due to the increased risk of heart attack. Examination of the advisory committee members who voted on Vioxx and similar drugs found that 10 of the 32 committee members had financial ties to the firms concerned (Camara and Kyle, 2015).

2.2. Shallow vs. Deep Capture

Despite the appeal of the existing economics literature on regulatory capture, academic articles coming out of law schools, suggest that this is only part of the story - specifically, a distinction is made between “shallow” and “deep” capture. To understand the difference, it is useful to start with the following description of Stigler’s (1971) view of regulators:

“...Stigler contested the reassuring conventional wisdom that our institutions are neutral and well-functioning and rejected the idea that the stated goals of regulators are

controlling. He did so by downplaying dispositional factors and emphasizing situational factors...” (Hanson and Yosifon, 2003, p.205)

Key to this description, are the concepts of *disposition* and *situation*. Dispositional attribution explains behavior in terms of the internal characteristics within an individual, as opposed to situational influences external to that individual. In other words, regulators are not dispositionally motivated to serve the public interest, rather they are subject to external influences, and therefore subject to capture. To use the language of social psychologists, the notion of regulators as benevolent social planners is subject to the bias of *fundamental attribution error*. Adapting Hanson and Yosifon (p.136): in analyzing the behavior of regulators, economists prior to Stigler were underestimating the role of situational influences, and overestimating the influence that regulator’s individual dispositions have in explaining the behavior of regulators.

Interestingly, legal scholars, while acknowledging that Stigler recognized the role of situation, also criticize the approach as giving too much of a role to the disposition of the regulator (Hanson and Yosifon, footnote 282, p.205). As indicated in the previous section, the now orthodox approach to regulatory capture post-Stigler assumes that the regulator is a rational maximizing agent, i.e., they may have an incentive to collude with firms. Obviously this is not in the public interest, and so the focus of the literature is on how a social welfare-maximizing government can write a collusion-proof contract inducing the regulator not to lie, at the same time as offering a contract to the firm that reduces the incentive to collude with the regulator.

In the case of regulation of a natural monopoly, Bó’s (2006) representation of the agency problem generates a key result that the regulator should be provided with a payment (wage) as an incentive to truthfully report when the firm’s costs are low, where the payment is greater than the value of the informational rents adjusted for any costs the firm incurs in making a side payment (bribe) to the regulator, and assuming the reservation wage of the regulator is zero. However, if the reservation wage of the regulator is non-zero, and there are extensive costs of auditing the

reports of the regulator, payment of wages may be either too costly or infeasible and the harder it will be to combat collusion between firm and regulator. Following Olson (1965), the costs of making side payments to the regulator include any organizational costs, which increase in the number of firms being regulated. Organizational costs will of course be minimized in the case of a natural monopoly, but it is still the case that the lower are other costs of bribery to the firm, the more likely that the regulator will actually be corruptible.

For the remainder of the current paper, it is assumed that members of advisory committees appointed by regulatory agencies may have incentives to collude with firms from the industry that they are regulating, and this will be denoted as *shallow capture*. Specifically, this is assumed to mean that members of advisory committees may learn about the actual safety of novel food products, but due to conflicts of interest, they will not always reveal that information to the regulatory agency, and as a result unsafe food product innovations can enter the market.

Hanson and Yosifon do in fact denote Stigler's contribution as one describing the process of shallow capture, as distinct from what they term *deep capture*. In their view, deep capture is one where firms seek to influence institutions beyond the regulator, including the media, public education and academic research, in order to ultimately influence the broader public. This definition has already found traction in an early application in agricultural economics by Smith and Tasnádi (2014) in their analysis of how the US food industry has attempted to influence the public debate concerning the causes of obesity. In the current paper, deep capture is assumed to mean that firms will present biased information in their applications for approval of novel foods in an effort to "nudge" members of the advisory board, and once approved firms will continue to disseminate this biased information in order influence consumers and other groups who maintain an interest in the safety of novel foods. By allowing for both shallow and deep capture of the regulatory process, we are accounting for both dispositional and situational influences to matter in the regulatory process, and that separating their effects is important.

3. Basic Model

3.1. Regulatory and Influence Structure

The regulatory and influence structure we have in mind is described in figure 1.

Figure 1 here

The government sets the rules for the regulatory body and any advisory committees they employ. For example, a novel food may be presumed unsafe until studies show otherwise, and a standard is then applied for approving that novel food for commercial release. Alternatively, a novel food may be “generally regarded as safe” (GRAS), unless evidence presented suggests otherwise. At this point, it is assumed that the government itself is not subject to capture due to the lobbying activities of the firm, consumers or other interest groups who may have an interest in the rules and standards applied for approval of novel foods. However, in the absence of wages paid to advisory committee members, there is a potential for shallow capture of the advisory committees due to members having a conflict of interest, i.e., the committee member may either vote for approval of a novel food product if they have a financial tie to the firm sponsoring that product, or they may vote against approval of that product if they have a financial tie to an incumbent firm with a competing product. For example, Lurie *et al.* (2006) report in their study of FDA advisory committees between 2001 and 2004, that for 22 percent of committee meetings, more than 50 percent of the scientists at those meetings had a conflict of interest, and 23 percent of the conflicts of interest involved research support exceeding \$100,000, and 44 percent of conflicts of interest involved lecturing fees/honoraria exceeding \$10,000.

The advisory committees are also subject to deep capture by the firms whose novel foods they are evaluating for approval. Treating presentation of the information as the diagnosis stage for a credence good, the innovating firm is assumed to be the “mechanic”, the innovator knowing more than the advisory committee about whether the “car needs repairing”, i.e., the novel food actually meets claims made about it and is safe. Essentially, innovations are novel by definition,

and experts hold asymmetric information about their innovations. As a consequence, food firms expend resources to “nudge” the regulator into approving their novel food product by providing biased information to advisory committee members.¹ We quote the following in support of this notion of bias due to deep capture,

“...Pharmaceutical companies are skilled at manipulating data in ways that cast their products in a favorable light...the drug manufacturer holds back the ninety five percent of the trials that show the product’s inefficacy. At the same time, it publishes the five percent of trials that attest to the drug’s usefulness...Another common ploy is to truncate data. If a clinical trial lasts for two years and the results show that a given drug is ineffective, industry scientists simply look at smaller chunks of data...” (Iuliano, 2010, pp.80-81)

Deep capture occurs because the advisory committee members, given their existing knowledge of food products, and the biased information they receive from firms, are subject to fundamental attribution error when approving novel food products that might actually prove harmful to consumers: they believe they are making the correct decision based on their disposition to act in the public interest when in fact they are subject to situational influence. In addition, the cost of deep capture falls with the extent of innovation by firms, i.e., there are economies of scope between innovation and influence. The more novel a food product, the more complex the diagnosis stage, and the less able advisory committees are able to seek a second opinion and the system is therefore committed to moving to the treatment stage (Dulleck and Kerschbamer, 2006).

3.2. Firm-Regulator Timeline

The firm is assumed to invest in developing a novel food product f , and the regulator is assumed to be able to observe that $f > 0$, due to the fact that the once the firm is successful, it either seeks

¹ It should be noted that there is a political science literature concerning provision of information to regulators. For example, Calvert (1985) considers the case where regulators may prefer to use biased advisers, due to the fact that they may be a more credible source in difficult choice situations where mistaken choices could be very costly.

a patent on its innovation and/or it implements an observable new production process. In developing the novel food product, the firm also generates data about the safety b of its innovation. Once the firm has observed b , which is unobserved by the regulator, it invests in deep capture D . At this point, there are two possible outcomes: (i) if $f > 0$, and no data are submitted to the regulator, the regulator denies commercial approval of the food product – this follows from the fact that the regulator either observes a patent application and/or a new production process is started; (ii) if $f > 0$, and data are submitted to the regulator.

Assuming $f > 0$, and b is submitted in an application for approval, the regulator, through an advisory committee, assesses the novel product for its claimed safety, based on the rules for approval already established by the government, and using scientific and statistical techniques influenced by the firm's investment in deep capture. We conceive of deep capture of the advisory committee in terms of the stylized representation in figure 2. At time t , the advisory committee receives a signal from the firm, $\tilde{b}_t^i = b_t^i + \varepsilon_t^i$, ($D_t \in [0,1]$), where \tilde{b}_t^i is the signal of true safety b_t^i , subject to an error term $\varepsilon_t^i = \mu_t^i + \varphi_t^i$, where μ_t^i is statistical noise and φ_t^i is bias, the latter depending on whether or not the firm invests in deep capture, $D_t \in [0,1]$.

Figure 2 here

Given this structure, we can distinguish between two cases:

(i) True quality has not decreased, $b_t^i = b_{t-1}^i$, i.e., previous samplings do not indicate a significant decline in safety of the novel food, relative to some existing benchmark. With investment in deep capture, $D_t=1$, there is some bias φ_t^i from an outlier being “nudged” closer to the remaining samplings, b_{t-1}^i , and even though noise μ_t^i is reduced, it does not change the overall signal \tilde{b}_t^i to advisory committee members.

(ii) True quality has decreased, $b_t^i \neq b_{t-1}^i$, i.e., previous samplings indicate a significant decline in safety of the novel food, relative to an accepted benchmark. With investment in deep capture, $D_t = 1$, there is significant bias φ_t^i as the previous samplings distributed around δb_{t-1}^i are nudged closer to b_{t-1}^i , such that $\delta b_{t-1}^i < \tilde{b}_t^i < b_{t-1}^i$, but noise in the signal μ_t^i does not change.

If the advisory committee votes in favor of approving the novel food product, the regulatory agency informs the firm of its safety assessment, and the firm then chooses whether or not to implement the innovation commercially, which is observed by the regulator. At this point the regulator communicates product quality to consumers, who treat the quality assessment as true quality, and make their purchases according to the price/quality combination of the firm.

4. Voting in Advisory Committees and Regulatory Capture

The firm submits data b to the regulatory agency concerning the quality and safety of its novel food i in application a , for which it is seeking approval. The regulatory agency initially conducts an internal review of these data, which it may then refer to an advisory committee of scientists who have some knowledge of the field relating to the novel food. After presentation of these data, the advisory committee members vote for or against approval of the application. The regulatory agency then follows the recommendation of the advisory committee on whether the novel food can be commercially released. Our interest here is in analyzing the voting behavior of members of an advisory committee, and how shallow and deep capture may affect the voting process. We appeal to recent analysis of the voting behavior of US Supreme Court judges by Iaryczower and Shum (2012), which has also been adapted and applied to voting behavior of FDA advisory committees on new drug applications (Camara and Kyle, 2015).

An advisory committee is made up of m scientists, $j=1, \dots, m$, who have to vote on A independent novel food applications, $a=1, \dots, A$. For each application a , a committee member can vote for or against approval, $v_j^a \in \{0, 1\}$, with $v_j^a = 0$ being a vote against, and $v_j^a = 1$ a vote

for approval. The advisory committee then aggregates the votes of all committee members by a rule such as majority rule, i.e., the committee votes in favor of the novel food application, $v^a = 1$, if $\sum_j v_j^a \geq R \equiv (m+1)/2$, and against the application if $v^a = 0$.

Prior to voting on an application, each committee member j observes a private signal, $s_j^a = \omega^a + \sigma_j^a \psi^a$, where $\psi^a \sim N(0,1)$. $\omega^a \in \{0,1\}$, is an unobservable variable indicating the correct decision about the safety of a novel food, i.e., the correct decision that it is safe $\omega^a = 1$, and the correct decision that it is unsafe $\omega^a = 0$. $\theta_j^a = 1/\sigma_j^a$ is a scale parameter that measures the information content of the signals received by committee member j , where the information structure satisfies the Monotone Likelihood Ratio Property (MLRP).

Each committee member cares about the information contained in the signal, as their payoffs are state-dependent. Specifically, it is assumed that given $\pi_j^a \in (0,1)$, a committee member's payoff depends on both the correct decision about a novel food, ω^a , and their actual vote on the application for approval, v_j^a . Specifically, there are two possible negative payoffs to a committee member if they get the decision about safety of a novel food wrong:

- (i) The cost to a committee member of recommending an unsafe novel food for commercial release is $-\pi_j^a$, given that they vote in favor of the application, $v_j^a = 1$, but the correct decision is actually that the novel food is unsafe, $\omega^a = 0$.
- (ii) The cost to a committee member of blocking a safe novel food for commercial release is $-(1-\pi_j^a)$, given that they vote against the application, $v_j^a = 0$, but the correct decision is actually that the novel food is safe, $\omega^a = 1$.

These negative payoffs are also adjusted to allow for the possibility of conflicts of interest on the part of the advisory committee member, i.e., there is the potential for shallow capture. If a committee member has a tie to the firm sponsoring an application, SC_j^a , they receive λ for voting in favor of the application, and if they have a tie to a competing firm, CC_j^a , they receive κ for voting against the application. Finally, the payoffs of $v_j^a = \omega^a = 1$, and $v_j^a = \omega^a = 0$ are normalized to zero.

Information E consists of the private scientific information of the committee member, which is subject to influence by the firm through \tilde{b}_j^i , along with the possibility that the committee member believes they are pivotal in determining the committee's decision. Assuming initially that there are no conflicts of interest, $\lambda = \kappa = 0$, an advisory committee member will vote in favor of approval of a novel food product iff $\Pr_j(\omega^a = 1 | E) \geq \pi_j^a$. Equivalently, and allowing for conflicts of interest, an advisory committee member will only vote in favor of approval iff the likelihood ratio $L(E)$ exceeds a threshold:

$$L(E) = \frac{\Pr_j(E | \omega^a = 1)}{\Pr_j(E | \omega^a = 0)} \geq \frac{\pi_j^a + \kappa CC_j^a - \lambda SC_j^a}{(1 - \pi_j^a) + \kappa CC_j^a - \lambda SC_j^a} \cdot \frac{1 - \rho^a}{\rho^a} \quad (1)$$

where $\rho^a \equiv \Pr(\omega^a = 1)$ is the committee members' common prior probability of the unobserved state, ω^a .

If committee members care only about their own vote (the expressive voting model), they vote based only on their private information, $E = s_j^a$, i.e., they rule in favor of approval whenever, $\Pr_j(\omega^a = 1 | s_j^a) \geq \pi_j^a$. Consequently, advisory committee member j votes in favor of a novel food application a when:

$$L(s) = \frac{\Pr_j(s_j^a | \omega^a = 1)}{\Pr_j(s_j^a | \omega^a = 0)} = \frac{\phi(\theta_j^a [s_j^a - 1])}{\phi(\theta_j^a s_j^a)} \geq \frac{\pi_j^a + \kappa CC_j^a - \lambda SC_j^a}{(1 - \pi_j^a) + \kappa CC_j^a - \lambda SC_j^a} \cdot \frac{1 - \rho^a}{\rho^a} \quad (2)$$

Let $(s_j^a)^{exp}$ be the value of s_j^a that solves (2) with equality. By the MLRP, $L(s)$ is increasing in s , such that a committee member will vote in favor or approving the application whenever $s_j^a \geq (s_j^a)^{exp}$.

From this model structure, it is possible to make some predictions about the influence of shallow and deep capture on the votes of advisory committee members, and hence the outcome of committee voting. The parameter π_j^a can be thought of as capturing the “ideological” beliefs of a committee member about novel foods. If their beliefs are neutral, $\pi_j^a \approx 1/2$, and the common prior is uninformative, $\rho^a \approx 1/2$, if the information content of the signal is “good”, i.e., the scaling parameter θ_j^a is high, and there are no conflicts of interest, $\lambda = \kappa = 0$, then advisory committees will come to unanimous decisions, and be evenly split between approving and rejecting novel foods. This is the case where there is neither shallow nor deep capture, i.e., committee members are not subject to bribes, and “good” information is not subject to bias, i.e., the firm does not try to convince a neutral committee member that their novel food is actually safe when it is in fact unsafe.

If these assumptions are relaxed individually: first, suppose committee members have strong “ideological” beliefs. For example, suppose the class of novel food is one containing genetically modified (GM) ingredients, and the advisory committee member is either pre-disposed to be in favor of GM ingredients, $\pi_j^a \approx 1$, or pre-disposed to be against GM ingredients, $\pi_j^a \approx 0$. In this case, individual committee members will exhibit a lower variability in their votes, voting more consistently for or against the novel food; second, if there is shallow capture due to conflict of interest, $\lambda > 0$ and $\kappa > 0$, committee members are more likely to vote for the novel food of a sponsor, and more often vote against the product of a competitor to their sponsor; and third, if the sponsoring firm supplies biased information to committee members via deep capture

investments, there will be less variability in their voting, and they will more often vote with the majority in favor of approving novel foods.

5. Summary and Implications

The fundamental motivation for this paper is that agricultural economists have only focused on the treatment stage of the credence good problem, ignoring the idea that firms are experts at the diagnosis stage when they bring their innovations to commercial application. Importantly, in the case of novel foods, it is typically a regulatory agency that is responsible for making decisions about moving from diagnosis to treatment. As a consequence, there is potential for capture of regulatory agencies in their evaluation of the claimed quality and safety of food industry innovations. Capture can be conceived of at two levels: first, even with complete information about a novel food, a regulatory agency, through its scientific advisory committees may be subject to shallow capture as a result of conflicts of interest on the part of advisory committee members. This idea draws on the orthodox literature on regulatory capture, whereby firms and regulators have an incentive to collude over not revealing relevant information to the policymaker. Second, given the complexity of innovations, scientific advisory committees are also subject to deep capture. In this case, firms have an incentive, due to economies of scope between the extent of innovation and the cost of influence, to expend resources on capture through providing biased information about product safety in an effort to nudge scientific advisory committees towards voting in favor of a novel food application. Analysis of the voting behavior of advisory committees suggests that their voting decisions can reflect both shallow and deep capture.

In terms of policy implications, there are two obvious steps that governments could take in their approach to the supervisory role of regulatory agencies. The first, which comes directly from the orthodox literature on regulatory capture, is to minimize the impact of conflicts of interest. The available empirical evidence is actually mixed on the impact of shallow capture; for example, Lurie *et al.* (2006) found that excluding FDA advisory committee members with a conflict of



interest from votes would have reduced the number of votes in favor of a new drug application, but not enough to change the approval outcome. In contrast, Golec and Cooper (2015), find little evidence that conflicts of interest lead to decisions in favor of pharmaceutical firms' interests. Second, deep capture might be minimized through “taking industry out of safety trials” through independent conduct of safety trials (Iuliano, 2010, pp.80-87), e.g., either the regulatory agency itself could employ its own scientists to conduct such trials or they could be outsourced to scientists at universities and other research centers. Of course, the cost of the former may be prohibitive, and the latter institutions are themselves open to capture.

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Figure 1: Regulatory and Influence Structure

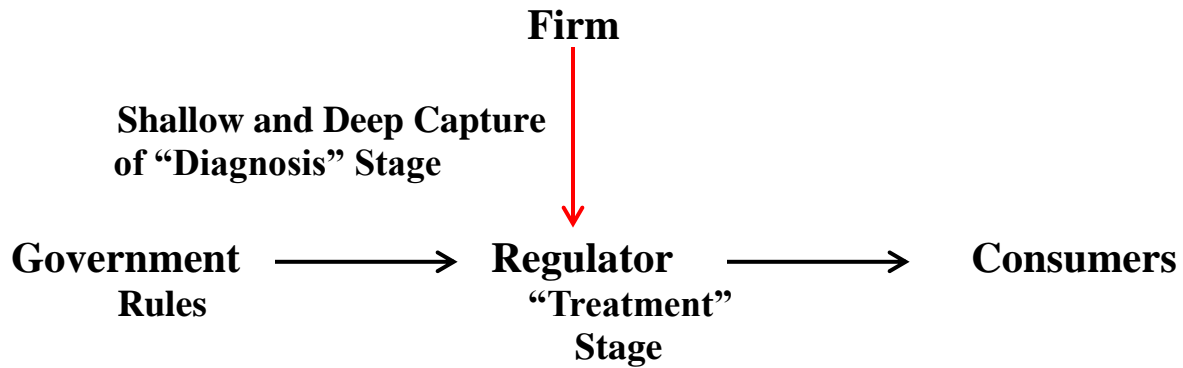


Figure 2: Firm Influence on Regulatory Assessment of Safety Samples

