Combating Antimicrobial Resistance:
Regulatory Strategies And Institutional Capacity

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Amnesia is a common, important, but rarely noted side effect of antibiotics. Apart from medical historians, few recall the severe morbidity and mortality once associated with acute bacterial infection. However, decades of antibiotic overuse and misuse have compromised the long-term availability and efficacy of these life-saving therapies. If designed and implemented appropriately, regulation can reduce the risk of bacterial infection, reserve antibiotics for circumstances where they are necessary, and rationalize the use of the most powerful agents. Regulation of antibiotic resistance can be justified, and should be guided, by both efficiency and fairness. A range of regulatory options are available – some information-based, some incentive-based, some command-and-control – each of which has indications, strengths, and weaknesses. A desired set of regulatory strategies must then be matched with the appropriate legal and regulatory institutions. A renewed focus on regulatory and institutional design has significant potential to reduce antibiotic-resistant bacterial infections and increase the effective life of existing and new antibiotics.

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Amnesia is a common, important, but rarely noted side effect of antibiotics. Apart from medical historians, few recall the severe morbidity and mortality once associated with acute bacterial infection. Some may know that pneumonia was once called “the old man’s friend,” but who remembers that Osler described it as the “captain of the men of death”? Puerperal (childbed) fever used to kill almost twenty thousand women every year, but is now largely a historic curiosity. People with a persistent cough do not consider which sanatorium they should go to for a rest cure, or worry that they have received a death sentence – even though in 1900, pneumonia and tuberculosis were the two leading causes of death in the U.S.²

Before the rise of antibiotics, the risks of an early death lurked around every corner. In 1924, President Calvin Coolidge’s son died of sepsis when he got a blister on his foot after playing tennis on the White House lawn.³ Twelve years later, President Franklin Roosevelt’s son developed a “septic sore throat.” He was treated with a newly-discovered sulfa-based antibiotic, and recovered.⁴

The first civilian life was saved by penicillin in 1942, after all other treatments had failed. Penicillin allowed her to live another fifty-seven years.⁵ First-generation cephalosporins were introduced in the mid-1960s; broader spectrum second and third-generation cephalosporins followed.

These drugs transformed the treatment of bacterial infection. In 1969, William H. Stewart, the U.S. Surgeon General, reportedly declared “it is time to close the book on infectious diseases.”⁶ Life before the discovery and commercialization of antibiotics now seems as distant as the Jurassic era. Unfortunately, persistent misuse and overuse of antibiotics places our future at risk, as antibiotic resistance has become a major public health threat.⁷

² http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4829a1.htm
³ Roger Budd, Penicillin: Triumph and Tragedy 4 (2007)
⁴ Prontosil, Time, Dec. 28, 2936, at http://www.time.com/time/magazine/article/0,9171,771900,00.html
Although MRSA (methicillin-resistant Staphylococcus aureus) attracts most of the media attention, serious risks are raised by other drug-resistant organisms, including VRE (vancomycin-resistant enterococci) and multiple drug-resistant Klebsiella. Because MRSA is treated with vancomycin, the emergence of vancomycin-resistant staphylococci (VRSA) is a worrisome sign. Barring significant changes, we run a substantial risk of returning to a world where bacterial infection causes tens of thousands of premature deaths.

Federal and state regulators have not ignored these issues, but they have had limited success in solving them. A March 2008 GAO report stated that it was difficult to be certain about the scope of the problem (which is itself a problem), and that federal efforts were uncoordinated and had not effectively addressed healthcare-associated infections ("HAIs"). A subsequent GAO report catalogued reporting initiatives at the state level and efforts by individual hospitals. In response, DHHS announced a national action plan, extending and revising a similar plan announced seven years earlier. Other recommendations have been made by professional societies, public health organizations,

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For a collection of such articles, see http://www.stophospitalinfections.org/newsroom.html.


and think tanks, and various efforts are under way within particular communities and internationally. Law professors have written on these subjects as well. Prompt action in many legal and policy arenas is necessary, and it is natural and proper that these endeavors begin in familiar territory. To select the most effective methods, however, it is important to survey the forest of options that regulatory theory makes available, as well as to examine the individual trees represented by existing programs and institutions.

Our goal in this paper is to provide policymakers with both a map of the regulatory landscape and a compass for using particular institutions to address antibiotic resistance. We do not attempt to summarize the massive clinical and economic literature on antibiotic resistance, nor do we argue for a specific reform strategy as a “magic bullet.” Instead, we seek to provide a theoretical and practical framework for choosing among regulatory strategies and for matching strategies with institutional capacity.

Part I applies regulatory theory to the issue of antibiotic resistance. Part II lays out a broad range of regulatory options. Part III discusses the public and private institutions through which these regulatory reforms could be deployed. Part IV offers suggested starting points for regulation. Part V concludes.

I. The Normative Case for Antibiotic Regulation

What, exactly, makes antibiotics an appropriate subject for government intervention? Antibiotic regulation is most often justified on efficiency grounds, implying that current practices fail to achieve socially optimal outcomes. An analogy can be made to pollution control: government is asked to curtail or modify beneficial private activity to prevent spillover public harms. As with pollution control, moreover, there is an important aspect of distributional fairness to reducing infectious disease by preserving antibiotic effectiveness. Other recognized social values, such as individual liberty and social solidarity, are also relevant to the analysis. Finally, a compelling argument for new regulation is that a huge amount of health care regulation already exists – and often creates perverse incentives for antibiotic (over-use and mis-use, undermining the the preservation of antimicrobial effectiveness.

A. Demand-side Efficiency

The fading effectiveness of antibiotic drugs against disease-producing bacteria is typically framed as a problem of social inefficiency. In a formulation that obscures almost as many issues as it clarifies, it is said that we engage in “unnecessary” use of the


antibiotics we have, while failing to develop new ones. In utilitarian terms, this implies that a different allocation of society’s protective and curative resources would provide greater total benefit in the fight against infectious disease.

From an analytical perspective, antibiotic resistance is the result of interactions among four distinct efficiency-based problems: misuse, overuse, containment, and prevention. These problems are not all under the control of health care providers, and they result from a mix of individual information shortfalls, agency failures, collective action problems, and externalities. The following discussion focuses on the demand side (infection and antibiotic use), after which we comment briefly on the supply side (antibiotic development).

1. Misuse

Antibiotic misuse is widespread, and imposes both direct harms on treated patients and spillover harms on future patients. Misuse takes various forms, the most common of which is physicians prescribing antibiotics when they are useless – most often because the patient suffers from a viral rather than bacterial infection. Another form of misuse is prescribing the wrong antibiotic for the bacteria infecting the patient. A third is prescribing the right antibiotic in the wrong dose. The risk of creating drug resistance is increased by both extended exposure and sub-therapeutic dosing or duration of treatment. Patients can contribute to this problem by failing to complete the specified course of treatment (if it is science-based) or, at least as often, by completing that course (if the prescribed treatment is based on habit or superstition, or is excessive).

Misuse generally arises from faulty individual decision-making, typically caused by lack of information and/or cognitive misperceptions of risks and benefits. Misuse attributable to non-compliance is particularly difficult to address, because direct monitoring of compliance is impractical, and the behavior of physicians and patients is often based on guesses that each makes about the other’s motives and conduct.

2. Overuse

Overuse of powerful antibiotics harms current and future patients with serious infections. Consider the use of “big-gun” antibiotics against routine organisms or at sites of infection that could be effectively treated with more ordinary drugs. Using powerful agents such as vancomycin or ciprofloxacin on bacteria susceptible to penicillin or tetracycline risks the development of resistance to the former, with potentially disastrous consequences for other patients suffering from rare but life-threatening diseases. However, successful application of narrow-spectrum or weaker drugs often requires sensitivity testing, which delays patient care and adds expense (offset to some extent if a cheaper drug can ultimately be employed).

In these situations, individual and collective efficiency may diverge, as a strong antibiotic may indeed be preferable for the treatment of each particular infected patient, even if it results in adverse consequences for future patients. There are also strategic incentives for immediate, indiscriminate antibiotic use: the glass-half-full belief that one’s own failure to conserve is riskless if everyone else acts properly (as with refusing vaccination), and the glass-half-empty belief that there is no point to one’s acknowledging the need for long-term availability if everyone else ignores it (as with dirtying a public restroom).
3. Containment

Preventing the spread of drug-resistant organisms is an essential strategy in controlling antibiotic resistance. Hospitals and nursing homes routinely house both patients infected with resistant bacteria and non-infected (but susceptible) patients, and then frequently fail to observe basic principles of infection control such as hand-washing, gowns, sterilization of equipment, and physical separation of those infected with antibiotic-resistant bacteria. Adherence to such protocols reduces the need for antibiotic treatment, the emergence of resistant strains, and the transfer of resistance from one strain to another.

Some of these process improvements require reconfigurations of physical space and protocols for sharing equipment and other medical resources, while others require behavioral changes among physicians, nurses, and other staff. Health care facilities vary in the degree to which they have addressed these issues. Although institutions suffer from some of the same collective action and externality problems that drive overuse, collectively beneficial choices may also be individually rational for institutions because they make decisions on behalf of groups of patients. This is particularly true if the payment system for medical care creates incentives for hospitals to keep patients free from infection – which, in general, it currently does not.

4. Prevention

A prevented primary infection requires no treatment – which of course lowers the risk of bacteria later developing antibiotic resistance. Occasionally, preventable infections occur because medical care was not sought early or because the wrong care was administered. More often, such events are a matter of public health: dirty water, contaminated food, inadequate sanitation, poor hygiene, etc.

Environmental factors of this sort are seldom under the control of medical providers. Many represent failures of collective action, not faulty individual decision-making. Funding for public health is often suboptimal because of political factors, even if there is bona fide social consensus regarding its importance. As a result, effective measures to prevent infections are likely to require cooperation between generally well-paid health care professionals and facilities, and typically cash-strapped departments of public health and safety-net providers.
B. Supply-side Efficiency

Incentives to develop and market new methods for preventing and treating infectious disease are influenced by intellectual property rights, regulatory approval processes, private health insurance practices, and government-administered pricing in public programs. Pharmaceutical, medical device, and biotechnology companies are sources of medical innovation, which gives rise to new vaccines, antibiotics, diagnostic tests, and infection control devices. In the absence of intellectual property rights (principally patents), innovation is a public good that will be under-produced by private actors. However, patents do not fully solve incentive problems in health care. Products typically require government approval, and demonstrating safety and effectiveness to the Food and Drug Administration (FDA) is time-consuming, which imposes direct and opportunity costs while eroding the patent term.

Medical suppliers respond by focusing their efforts on products that will appeal to a broad market of paying customers. Because most antibiotics are prescribed for a short-course, the range of use must be substantial to generate the same revenue stream as a product for the treatment of a chronic illness. Broad-spectrum antibiotics are therefore attractive from a business perspective, while constraints on their use to avoid breeding resistance are not.

Somewhat different problems apply to vaccines. Vaccines are intended to be administered to a large and otherwise healthy population, so they are strictly scrutinized for possible safety hazards. However, the price that can be charged tends to be far less than the cost of the suffering they help avoid, although the large market allows development expenditures to be recouped from a large population.

C. Distributional Issues

Fairness considerations are often lost in discussions of market failures and their associated inefficiencies. Yet equity should enter the debate over antibiotic resistance at several junctures. Poorer individuals are often most exposed to infectious agents, and have the least access to health care. In the short run, efforts to reduce antibiotic overuse may further compromise such individuals’ likelihood of receiving treatment, and reduce the benefits of treatment if it is received. Expensive infection control measures may also be economically infeasible for providers serving the poor. Over the long run, preservation of therapeutic effectiveness may offset these regressive effects, if older, cheaper drugs retain their efficacy.

Thinking about fairness also helps bring structure to valuation issues that are sometimes finessed in efficiency discussions. Eliminating pure waste, such as the use of antibiotics for infections that are obviously of viral origin, is of universal utility. By contrast, imposing restrictions on one person’s antibiotic use in order to keep antibiotics available for another person raises questions about distributive justice (e.g., who should sacrifice how much, and for whose benefit). Should one account for the subjective value of reassurance associated with taking a very powerful drug, or only the objectively demonstrable potential for the drug to effect a cure? What discount rate should be

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applied to costs and benefits that occur at very different times -- likely across
generations? Should fairness focus on preserving the rights of the very poor, or of the
very sick, understanding that there is substantial but not total overlap between those
groups? And, given our usual belief in sparing no expense to save identified lives, what
value should attach to preserving access to treatment that is truly life-saving?17

D. Liberty and Community Considerations

Liberty is one of the founding principles of the United States, and it has independent
ethical and constitutional importance. As with equity, liberty and efficiency are typically
aligned when pure waste is eliminated, but not when one person is made to sacrifice for
another’s benefit. Recently, for example, legal scholars and the courts have debated
whether an individual’s “right to self-protection” might trump the government’s authority
to restrict access to medical care, even if those restrictions are imposed for collective
social benefit.18 Although the government’s lawful police power to curtail liberty in
order to contain infectious disease is clearly established, traditional public health
measures tend to mandate therapy rather than restrict access to it. Denying people
something they want and can afford to purchase is a different type of incursion on liberty
than compelling them to receive something they do not desire. This is especially true
when the negative results of the denial may be immediately visible – such as a patient
who fails to recover after receiving a less powerful drug – while the positive aspects to
preserving drugs for the future seem distant and speculative.

On the other hand, efforts to preserve antibiotic effectiveness are likely to resonate with
supporters of communitarian conceptions of government, who view the proper regulation
of common resource pools as a politically important commitment as well as one that
produces a long-term efficiency gain.19 One can also frame the antibiotic resistance issue
as a “global public good” involving norms of international governance.20 Such theories
emphasize the importance of deliberative processes that involve communities in projects
of self-governance and safeguard common resources from exploitation. Protection from

17 Clark C. Havighurst, Strategies in Underwriting the Costs of Catastrophic Disease, Law & Contemp.
Probs., 122, 140-41 (Autumn, 1976) (“It is difficult to improve significantly on the commonplace
observation that human beings cannot empathize with faceless abstractions and that “squeaking wheels” –
the complaints of known victims, such as the very vigorous lobbying of kidney-disease patients – not the
silence of statistical unknowns, will get the government grease. Spending “millions of dollars to save a
fool who has chosen to row across the Atlantic has external benefits” lacking from highway safety
spending.”)

(overruling panel decision that terminally ill patients had the right to access experimental treatments that
FDA had not approved); Eugene Volokh, Medical Self-Defense, Prohibited Experimental Therapies, and
Payment for Organs, 120 Harv. L. Rev. 1813 (2007).

19 Garrett Hardin, The Tragedy of the Commons, 162 Science 1243 (1968). See also David M. Patrick and
James Hutchinson, Antibiotic use and population ecology: How you can reduce your "resistance footprint,"
Foster and Hajo Grundmann, Do We Need to Put Society First? The Potential for Tragedy in Antimicrobial

20 Richard D. Smith & Landis MacKellar, Global Public Goods and the Global Public Health Agenda:
infections fits this category, particularly as it relates to future generations, social stability, and long-term economic prosperity. Terms that often attach to improving antibiotic potency, such as “stewardship” and “sustainability,” invoke this political and regulatory tradition.

E. Improving Existing Regulation

Modifying the regulatory strategies that have brought us to the current state of antibiotic affairs would undoubtedly have broader consequences, not all of which can be anticipated. However, doing so is an important and necessary part of forestalling the development of widespread antibiotic resistance, and of improving the treatment of infectious disease in the U.S.

Skeptics regarding government intervention often point to the inefficiencies and maldistributions that existing health care regulation creates, either because it was enacted at the behest of special interests or because it has been poorly designed and administered. In addition to providing a valuable caution for new regulation, this perspective offers an independent justification to those pursuing a reform agenda.

Many characteristics of the extensive regulation that currently exists predispose the U.S. health care system to rampant antibiotic resistance. Unlike European health systems that accept constraints in order to achieve universality, the principal commitment of government policies in the United States has been to promote the supply of health care services through subsidies for physician training, hospital construction, and both private and public health insurance. By and large, physicians are granted exclusive prerogative to access these physical and financial resources, are spared the need to organize their fragmented business structures, and are urged to follow an ethic of single-patient advocacy rather than social stewardship. Direct government control over medical practice is rare, notwithstanding the fact that government purports to assure the safety of medical products. For example, most “off-label” use of drugs or medical devices by physicians is permitted (and compensated by health insurance) even though initial marketing of a new product requires prior approval by the FDA.

Payment methods for medical products and services are established by government in connection with public insurance programs such as Medicare and Medicaid, and are heavily influenced by government even for private insurers. Health care providers (both physicians and hospitals) are almost always paid for what they do to a patient, and not for health gains that they actually accomplish. When complications ensue, providers are routinely paid even more to remediate them. Service providers and medical suppliers

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21 Lawrence Jacobs, The Politics of America's Supply State: Health Reform and Medical Technology, 14 Health Affairs 143 (Summer 1995).
respond to these incentives by providing more units of care, preferably high-margin, technologically sophisticated items that can be administered repeatedly.

Indirect influences on medical practice include restrictions on who may deliver health care services (by placing physicians at the pinnacle of the health professions hierarchy and prosecuting the unlicensed practice of medicine), and mandates on what services must be covered by health insurance (through coverage laws). These regulatory requirements also tend to favor the provision of large numbers of poorly coordinated services, with a heavy emphasis on prescription medication. Monitoring of cost and quality has also been quite limited. The most visible form of lay review, malpractice litigation, paradoxically reinforces physicians’ habits of excess by judging poor outcomes in hindsight to determine where care might have been insufficient.

II. Methods of Regulation

Regulation can take many forms, several of which are relevant to the problems of bacterial infection and antibiotic resistance. Politicians often talk about regulation as if it falls along a continuum of intrusiveness, with less intrusive forms inherently preferable. This rhetorical framing results from the primacy accorded individual freedom in American constitutional design and political rhetoric. As discussed below, the intrusiveness formulation is also the result of a preference for federalism, which favors localism over centralized direction. This section of the article arrays regulatory methods across a spectrum of government intrusion into private conduct. Information disclosure is less intrusive; financial incentives are moderately intrusive; command and control regulation and rationing are very intrusive. Our aims are to display the breadth of available regulatory strategy, to identify their strengths and weaknesses, and to explain why and how they are applicable to the problem of antibiotic resistance. We leave to policymakers the task of choosing among them.

A. Information Provision and Disclosure

Information provision is a common regulatory method. Although information provision imposes costs on regulated entities and taxpayers, it is generally considered less intrusive than other forms of government involvement. Information-based regulation appeals broadly across the political spectrum: conservatives regard it as respectful of private decisions and market processes, while liberals celebrate “transparency” and the “right to know.” The desirability of informational regulatory strategies depends on production-related factors such as the quality of gathered information, its lack of availability without government intervention, and its nexus with the desired real-world objective. Also relevant are user-related factors such as its salience to recipients, its manageability, its likelihood of accurate comprehension, and the existence of paths by which recipients can act on it.

1. Education on antibiotic use and infection control

A straightforward (and long-standing) approach to antibiotic resistance is for the government to produce and disseminate educational materials on the proper use of

antibiotics and best practices for infection control. These materials can be directed at both expert and lay audiences. Material of this sort principally addresses failures of individual decision-making, such as taking antibiotics for viral infections, and has been uncontroversial—albeit largely ineffective. The FDA’s February 2003 final rule requiring the labels of systemic antibacterial drugs to include information on antimicrobial resistance and prudent use exemplifies this approach.

Somewhat more difficult issues are presented if government-funded educational tools attempt to “correct” how individuals frame and value health risks and the associated benefits of prevention or treatment. Whether one chooses a strong antibiotic where a weaker one might well suffice can be seen either as a behavioral misperception (e.g., an irrational overestimate of the likelihood of suffering from “flesh-eating bacteria” based on salient media coverage) or as one’s personal preference that should be respected (e.g., a desire to minimize all risks to health if it can be done without undue effort or personal cost). Controversy may also arise with respect to the appropriateness of government educational programs that are intended to inculcate social norms of collective cooperation regarding the preservation of antibiotic effectiveness. Conflict over such strategies can be minimized by using information disclosure primarily to encourage public discussion, and by ensuring that all recommended behavioral changes have a strong scientific foundation.

2. Public reporting/disclosure

A different information-based strategy is to require individuals and entities to measure their degree of success or failure and publicize the results. Generally, public reporting/disclosure of adverse events focuses on outcomes (e.g., rates of post-operative infection), but it can also be used for process-based measures of performance (e.g., number of people receiving vaccination against pneumonia). Historically, reporting (to government or self-regulatory organizations) and disclosure (to private parties) have been considered distinct forms of informational mandates, but the Internet has largely collapsed these functions into a unitary concept of transparency. Disclosure can induce improvement by several mechanisms, each of which is associated with somewhat different requirements for the content, format, and manner in which information is produced and distributed. In addition, government can learn from the reports it receives—and from the public discussion that follows release of information—whether and how to implement more direct forms of regulation.

Information directed at consumers is intended to help them choose the health care that is best for them. Ranking hospitals according to their rates of avoidable infection, or of infections with drug-resistant organisms, may induce patients (or their physicians, or their

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25 Whether these strategies are uncontroversial because they are ineffective is a subject we leave for another day.
26 68 FR 6062, February 6, 2003. Of course, the difficulty is that the label is aimed at the physician, but is likely to be reviewed, if at all, by the patient.
health insurers or employers who sponsor coverage) to select “better” health care providers. The belief that this might happen (a demand-side effect) in turn motivates hospitals and physicians to do a better job in addressing these problems (a supply-side effect). Although the two are obviously inter-related, there is better evidence for supply-side effects than demand-side effects from information disclosure in health care.28

The effectiveness of a consumer disclosure strategy depends on recipients of information being in a position to select among health care providers, receiving accurate information about those providers, and incorporating that information into their decisions. It is unlikely that information about infections or antibiotic use will be sufficiently meaningful to have a large effect on patients’ choice of hospital given the urgency and emotional impact of a decision to seek medical care. However, because resistant infections can be fatal, it is possible that poor infection control could be a salient enough headline issue to serve as a proxy for overall hospital quality.

Patients want to know about their physicians. Unfortunately, information about the infection rate among individual physicians may not be useful, as practice size is often too small for statistical reliability. Although patients may wish to know if their physicians are prescribing antibiotics competently, that determination will likely be time-consuming and controversial – as physicians will claim (sometimes correctly) that complex professional judgments are required. On the other hand, disclosure mandates can be used to help patients assess the reliability of their physicians’ recommendations – by requiring, for example, that information about physicians’ financial relationships with drug companies be made public. In the absence of direct regulation, consumer disclosure – perhaps in the form of a national publicly-accessible database – may help discipline the terms of these arrangements.29

On the whole, transparency is more likely to produce change through pathways other than consumer choice. Health care professionals take pride in their work, and generally strive to improve their performance. Information can help motivate these efforts if professionals perceive it to be reliable and important. Reporting and disclosure requirements can also assist government by benchmarking current practices so that feasible direct regulation can be implemented if needed. For example, hospitals or nursing homes with low levels of acquired infections can set the standard for other facilities. Insofar as the voting public feels that public institutions and political leaders should be protecting its long-term collective interest in keeping effective antibiotics available, information about antibiotic use, infection control, and drug resistance also can help monitor the effectiveness of government itself at performing these tasks.

It is worth understanding, of course, that transparency can be a two-edged sword. It often induces “practicing to the rule,” even when doing so creates collateral problems or risks.


29 Institute of Medicine, Conflict of Interest in Medical Research, Education, and Practice, April, 2009, available at http://www.iom.edu/Object.File/Master/65/981/COI%20report%20brief%20for%20web.pdf (calling for standardization and disclosure of certain information, and elimination of “problematic relationships” between physicians and industry.) We are skeptical that “problematic relationships” can be easily defined or that the definition can be readily operationalized – particularly because the specifics of the relationships will be routinely revised in response to the announcement of new rules.
For example, the adoption of a new quality measure – the time to first treatment with antibiotics for patients with community-acquired pneumonia – creates a substantial incentive for rapid administration of antibiotics, regardless of the degree of diagnostic certainty.\textsuperscript{30} This approach may or may not constitute optimal care from the perspective of those treated, but it assuredly worsens the problem of antibiotic resistance in the long run.

3. Information restrictions

Information-based regulation sometimes takes the form of restrictions rather than mandates. State attorneys general and the Federal Trade Commission routinely target false and deceptive advertising, such as “miracle cures.” Occasionally, regulation limits the dissemination of truthful information on the grounds that the intended audience is overly impressionable, as with marketing cigarettes to children. These interventions must be carefully designed so as not to violate constitutional guarantees of (commercial) free speech. Information restrictions may also imposed to prevent an adverse inference being drawn from silence, perhaps in order to protect the privacy of the subject.

Restricting marketing of broad-spectrum antibiotics on the grounds they should be reserved for severe/hard-to-treat infections is likely to prove difficult, even though such use is an important contributor to overall antibiotic resistance. Because these antibiotics are FDA-approved, restrictions cannot be justified as necessary to protect the safety of specific individuals receiving the information, but require justification on collective grounds of public welfare. Such strategies can easily run afoul of constitutional limitations on the abridgement of freedom of speech.

B. Price Regulation and Financial Incentives

The information-oriented regulatory approaches discussed above are usually placed on the low end of the intrusiveness spectrum, with command-and-control strategies on the high end. This section discusses incentive-based regulation, which occupies an intermediate position between advising people what to do and forcing them to do it. Incentives are usually applied through financial mechanisms that change the price of an activity. Implicit in this approach is the condition that the activity already be a subject of private transactions in an existing marketplace. When government is itself a very large buyer, as with Medicare and Medicaid, the structure of payments and the amount paid can act as de facto command-and-control regulation of the funded activity. Occasionally, as with pollution control permits, government actually creates both a marketplace and the products to be traded in it.

Price-based regulation has significant risks. As Hayek observed, the “marvel” of the price mechanism in competitive markets is that it quickly conveys information about supply and demand among many decision-makers without that information ever being gathered or consciously analyzed in one place.\textsuperscript{31} Financial incentives that are justified by demonstrable inefficiencies in private markets may enhance welfare, and often require altering only a subset of informational signals rather than subjecting an entire market to


\textsuperscript{31} Friedrich Hayek, The Use of Information in Society, 35 American Economic Review 519 (1945).
centralized planning through command-and-control regulation. However, price interventions that are not efficiency-justified, or that create imbalances between supply and demand, can disrupt information flow in counterproductive ways.

On the other hand, medical prices in the United States are already higher than a competitive market would produce. These prices are in part the result of long-standing regulatory restrictions on price competition and competitive entry, including licensing laws, corporate practice of medicine prohibitions, public purchasing practices, and private insurance mandates. Not surprisingly, limitations on price competition—typically in conjunction with third-party payment—produce competition along non-price dimensions. In American medicine, this has usually taken the form of unverifiable professional assertions of “high quality” by individual physicians, and investment in ancillary services (e.g., office-based procedures and imaging equipment), which leads in many cases to overuse of medical care and high rates of complications, including infection.

Limitations on competitive entry create slightly different problems. Physicians in primary care settings must see large numbers of patients each day to achieve their target incomes, and giving a prescription (particularly an antibiotic) is a way to terminate a visit quickly without making the patient unhappy. Partly for this reason, settings that employ lower-cost nurse practitioners who can spend more time with each patient often generate fewer unnecessary prescriptions. Excessive prescriptions can also result from poorly designed systems of government-administered pricing. In Japan, for example, artificially low government reimbursement for basic office visits resulted in physicians prescribing grossly inappropriate amounts of medication because they were permitted to dispense the drugs themselves at a substantial markup.

Encouraging price competition is an important regulatory option—particularly if it triggers a restructuring of health care delivery to make inexpensive primary care widely available. Competitive pricing for basic medical care might well improve the rationality of individual antibiotic use, although it would not necessarily reduce true problems of collective action that increase bacterial resistance. A slight risk is that making health care more affordable might actually increase antibiotic overuse. Stated bluntly, a patient who receives an “unnecessary” prescription for an antibiotic is more likely to have it filled if it costs $4 at Wal-Mart (or is free at Giant) than if it costs $25 at the local drugstore. Whether this turns out to be a serious problem depends on many factors, including the price of antibiotics, the rate of “unnecessary” prescriptions, whether discounts apply to broad-spectrum, powerful antibiotics or only simpler drugs, the extent to which outpatient rather than inpatient use is the source of resistance, and the cost of infection prevention, diagnosis, and control in both of these settings. However, infectious disease specialists have expressed concern about reduced-cost prescription drug programs.

33 Naoki Ikegami, Japanese Health Care: Low Cost Through Regulated Fees, 10 Health Affairs 87 (Fall 1991).
1. Pigovian taxation of externalities

Raising the price of a privately traded good to induce consumers to take full account of the cost associated with its use is perhaps the most common financial intervention. This so-called Pigovian taxation is most effective when demand is elastic, so that purchasing at the margin declines substantially for each increment in price. A second-best approach, valuable when demand is inelastic, is to apply revenue from a Pigovian tax to mitigate harms that result from over-consumption. This logic informs the efforts by public health professionals to use the amounts raised by taxes on tobacco to fund smoking cessation programs, health education, and smoking-related medical care.

Pigovian taxation is typically imposed when personal consumption inflicts harms on third parties. However, it can also supplement information disclosure when individuals misperceive risks to themselves or value them inaccurately. The politics of Pigovian taxation vary. Taxes on personal indulgences (e.g., smoking and drinking) are more publicly acceptable than other explicit taxes, but have usually been enacted as revenue-raisers (and regressive ones at that) rather than true deterrents.

Direct Pigovian taxes can be used to raise the price of antibiotics and reduce their use. Targeting assessments is likely to prove challenging, however. Tax rates should reflect the marginal disutility of particular drugs in particular situations, and should be highest for high-harm uses. One strategy is to impose high tax rates on broad-spectrum or powerful antibiotics. In theory, this approach does not require government to tax more when benefit to the buyer is less (e.g., an antibiotic prescribed for a viral infection), because the consumer is assumed to balance personal benefit against personal cost. Still, a public process would be needed to determine which antibiotics would be subject to relatively more or relatively less tax, to decide which necessary uses would be exempt, and to determine (likely by trial and error) what tax rates are needed to change antibiotic consumption rates. Any given tax structure will be imperfect along some relevant dimensions, since clinical variation and informational asymmetries ensure that one size will not fit all.

Distributional consequences may also be material. With a uniform tax rate, less wealthy consumers are more likely to forgo necessary antibiotics, while wealthier consumers are likely to continue unnecessary overuse.

The level of trade at which the tax should be collected is also problematic. Should drug manufacturers, hospitals, physicians, or patients be assessed? Taxes are usually imposed in the manner that will generate the greatest compliance at the lowest enforcement cost, and with the least political fallout. Price elasticities generally divide the economic burden (tax incidence) between sellers and buyers, regardless of where the locus of collection is placed. However, the number of payment intermediaries in health care makes the initial placement decision for any tax non-trivial.

2. Tradable permits

 Tradable permits are a theoretical alternative to Pigovian taxes. Permits are most useful when the public interest requires an aggregate reduction in consumption, the individual

costs of reducing consumption vary widely, and price elasticities of demand are
unknown. Government could establish a tradable permit system for certain high-value
antibiotics, with large penalties applied to unpermitted uses. In concept, this is attractive
because antibiotic overuse and misuse are national problems, individual antibiotic
prescriptions vary greatly in their likely effectiveness, and prescribers are better situated
than regulators to know whether each prescription is strictly necessary.³⁵

Health care providers also have other means for reducing antibiotic use than forgoing
prescription, such as improved infection control. In a permit system, hospitals that could
prevent infections cheaply would sell permits to others that could not (e.g., those located
in communities with high infection rates), allowing overall antibiotic use to be reduced
by the desired amount at the lowest possible cost. Because of enforcement costs, a
permit system is most easily applied to a small number of participating users, such as
large hospitals. As in all permit systems, leakage of antibiotics from regulated to
unregulated sources must be policed, and regulators must be alert to unintended
inequities and inefficiencies, such as “hot spots” for infection.

The initial allocation of the permits – whether they will be sold or assigned, and if the
latter, on what basis – creates additional complexities. Assignment reflects the reality
that some hospitals and physicians treat patients with a greater risk of infection, but
confers a valuable asset on institutions that currently have higher infection rates – some
of which might be avoidable. An auction allows hospitals that value permits the most to
secure them directly from the government, while simultaneously raising funds for the
government that can be put to a variety of uses. However, hospitals that lack the
resources to bid successfully for the permits might still have greater need for access to
antibiotics, given the patient population they serve.

Finally, permits will be less effective if some jurisdictions do not adopt them or some
uses within participating jurisdictions are exempted on political grounds. If this occurs,
overall antibiotic use will not be sufficiently reduced and some antibiotic use by
regulated sources will be converted into use by unregulated sources.

3. Subsidies

Public subsidies are a common fiscal-regulatory technique to encourage activities that are
under-supplied by competitive markets. Many of these activities fall into the analytic
category of “public goods.” The public subsidy can come in the form of cash transfers to
those who provide the public goods, restricted vouchers given to those who need the
services, or direct government provision of the services. All three strategies spread the
cost of the subsidy among taxpayers, market participants, or both. Increased funding of
public health activities directed at improved antibiotic use and infection prevention falls
into this category.

Explicit subsidies can be used to alter relative prices and therefore consumer behavior.
Subsidies for diagnostic tests are one possible intervention. Antibiotics are often
needlessly prescribed because bacterial infection is never verified, or a more powerful
antibiotic is given when testing would have revealed that a less powerful one would have

³⁵ See generally R.D. Smith & J. Coast, Controlling antimicrobial resistance: a proposed transferable permit
been equally effective. Subsidized testing might be particularly useful as an alternative to
direct control of practice in widely dispersed settings such as physicians’ offices.
Monitoring would be necessary to ensure that testing decreased antibiotic use, rather than
merely adding another layer of cost between the time a patient seeks care and the time a
prescription is generated.

Physician practices also tend not to make large capital investments. Subsidies for the
acquisition of health information technology, including decision-support software, might
courage physicians to adopt these systems. Such systems have the potential to improve
the use of antibiotics, as well to facilitate compliance with an information reporting or
disclosure regime if one were adopted.

Subsidies might also be offered for infection control systems in hospitals, although larger
institutions probably do not require dedicated funds in order to afford such
improvements. Unlike physician practices, enough money flows through the hospital
sector that marginal incentives will seldom produce substantial effects. Hospitals will
only alter their behavior if the financial implications are large.

One possible strategy is to condition the receipt of existing subsidies by hospitals
(including the tens of billions of dollars they receive in exemptions from income and
property taxes) on playing an active, verifiable role in improving infection control and
treatment in their communities. Federal tax law already requires that hospitals perform a
charitable function in their communities in order to retain their tax exemption. Instilling
in federal tax law a more detailed notion of “community benefit” as providing public
goods as well as offering free or reduced-price medical care to indigent patients could
induce hospitals to improve the use of antibiotics within their institutions, in the offices
of physicians with admitting privileges at the hospital, and in their service areas
generally.

An even more aggressive approach would be for Congress to tie its very large tax subsidy
for employment-based health coverage to the adoption of explicit purchasing strategies
designed to minimize antibiotic resistance. Once adopted, this approach would have both
direct and indirect effects. The direct effect would be to revamp private insurance benefit
packages and payment methodologies so as to reduce coverage of medical services that
needlessly increase the risk of antibiotic resistance, and to expand coverage of
interventions that might reduce resistance. The indirect effect would be to alter long-term
incentives for suppliers of innovative products, whether vaccines, diagnostic tests,
infection control systems, or new antibiotics.

Subsidies also raise obvious problems. Paying too little will result in an inadequate level
of subsidized behavior, while paying too much will be wasteful. It is particularly difficult
to determine the optimal level of the subsidized conduct (and hence of the subsidy) in the
absence of the price signals delivered by a well-functioning market – but if there were a
well-functioning market, there would be less need for a subsidy.

4. Prizes

A public monetary prize is a special form of subsidy designed to encourage and reward
innovation without committing to an indefinite stream of payment or conferring an
ongoing property right. Prizes might be awarded for new antibiotics, for novel ways to fight bacterial infections, or for replicable community strategies for prevention, detection, and control of spread. Prizes offer a more limited financial incentive than direct subsidies. On the other hand, the recognition and publicity associated with a substantial prize can help instill or reinforce professional and public norms about prudent stewardship of existing antibiotics. Prizes accordingly have the potential to encourage providers to adopt infection control strategies that less visible subsidies might not.

5. Property Rights

Subsidies can also be created by operation of intellectual property law. Expanding the duration of patent protection for new types of antibiotic, for example, might lessen pharmaceutical manufacturers’ incentive to promote immediate wide use of a drug, and focus instead on marketing those drugs only for otherwise untreatable infections. This approach would work best if only one company or one patent pool controlled all rights to a novel class of drug. An alternative strategy for restricting the use of new antibiotics to the most susceptible population is to award them orphan drug status, which confers preferential patent protection and other benefits as long as use is restricted. At the same time, patent policy could promote greater use of ordinary antibiotics by granting earlier access to those formulas by generic manufacturers.

Changes in intellectual property rights are generally not well suited to the fine-tuning of public policy with regard to antibiotics, because any reform is certain to be both under-inclusive and over-inclusive. However, such strategies may be more politically attractive than direct subsidies, because their costs do not appear in the federal budget.

5. Public purchasing, administered pricing, and price controls

When most people think about price regulation, they imagine government directly setting prices or capping the amount that can be charged. In American health care, direct price controls of this sort are uncommon. On the other hand, because half of total health expenditures in the U.S. are paid by federal, state, and local government, government can implicitly regulate prices through its purchasing practices. For political reasons, the prices at which government purchases health care are almost always set administratively (at first passively based on custom, now by statutory formula) rather than by competitive bidding. Private insurers routinely adopt similar methods or price in the shadow of public programs, taking account of local market conditions.

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37 See, e.g., Kades, supra note 15.
38 Congress has already recognized this possibility. In the Food and Drug Administration Amendment Act of 2007, section 1112 requires FDA to convene a public meeting “regarding which serious and life threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antibiotic-resistant bacteria, potentially qualify for available grants and contracts under section 5(a) of the Orphan Drug Act…or other incentives for development.” FDA held this hearing on April 28, 2008. http://www.fda.gov/OHRMS/DOCKETS/98fr/08-1129.htm.
The substantive conditions of participation in Medicare and Medicaid, including compliance with administered pricing, can become de facto command-and-control regulation if the government’s role is so large that health care providers cannot survive without accepting publicly supported patients. Private conformity with public administered pricing is also sometimes compelled by laws designed to protect the integrity of government purchasing. Fraud and abuse prohibitions, for example, make it difficult for health care providers to enter into many types of contractual arrangements with one another, or with third parties, even if those agreements do not specifically relate to federal health programs.

Medicare Part D – at least as it currently exists – represents an interesting example of public purchasing of pharmaceuticals because it builds on pricing models that were developed in the private sector such as tiering of consumer cost-sharing by drug class. This is a relatively hands-off approach compared to Medicare payment of physicians, hospitals, and durable equipment suppliers. It resulted from arguments made by the pharmaceutical and medical device industries to the enacting Congress that capping or benchmarking drug prices would discourage long-term innovation. Future Congresses attempting to close large budget deficits may be less receptive to this reasoning.

One can imagine using tiering strategies to address antimicrobial resistance, including greater consumer cost-sharing for antibiotics prescribed for marginal uses, and substantial surcharges for non-conforming uses of drugs placed on a “reserve list” for serious infections. At the same time, rewards to both pharmaceutical companies and physicians should be greater when the most powerful antibiotics are used on the sickest patients. However, it is impossible for antibiotic producers in a conventional market to receive more from a patient whose life is saved than from a patient who takes a product for a marginal or frivolous indication. An administered pricing system could redress this failure by ensuring higher reimbursement to the manufacturer or supplier for greater value received, with performance measured at the level of the health plan, or the county/state/country.

A tiering strategy would dovetail with existing initiatives to pay physicians based on their performance, while also maintaining the patient’s financial incentive to take antibiotics only to the extent they are clinically indicated. Although this strategy is intuitively attractive, it is at odds with larger market developments in the U.S., which seek to lower the cost of pharmaceuticals across the board (including by offering free or extremely low-cost generic antibiotics at major retailers).

A different set of administered pricing policies governs reimbursement to hospitals for the cost of treating additional illnesses acquired during a hospital stay. The Medicare program and several private insurers have already limited or eliminated payment for treatment of obvious medical errors, including avoidable hospital-acquired infections. The goal of these policies is to encourage hospitals to invest in early detection and control by removing revenue streams that previously made them financially indifferent to clinical complications arising from the care they provide. Conversely, if Medicare covers

40 Of course, these tiering strategies are not necessarily the optimal strategy for minimizing resistance. Design details matter in assessing the comparative performance of tiering v. alternative strategies.

41 See supra note 34.
(and separately pays for) screening of newly admitted hospital patients for infection, such screening is likely to become prevalent, if not the standard of care. If permitted by fraud and abuse law, hospitals might well adopt “gain-sharing” programs to encourage physicians to consistently order such screening, as well as to motivate compliance with antibiotic usage recommendations.

Finally, government can purchase antibiotics directly from manufacturers to be held in reserve rather than to be used. A strategic stockpile of effective antibiotics for use in case of widespread resistant infections is appealing at first glance, and would build on the precedent of the Strategic National Stockpile. However, as the negotiations over ciprofloxacin during the 2001 anthrax scare illustrate, there may be a narrow window between the payment amount that would be sufficient to make the program attractive to the company whose product is picked, and the amount that the government can afford as an immediate, on-budget expense. There is also an important difference (both practical and perceptual) between the government stockpiling antibiotics so as to deal with short-term supply dislocations in the event of a public health emergency, and the government removing a class of antibiotics from the market entirely against the prospect of a new infection emerging that is resistant to all other antibiotics. In the former instance, the government is just another (bulk) purchaser of the products; in the latter, it is expropriating the entire value of the antibiotic over its useful life-span, creating a “taking” that requires just compensation under the express terms of the 5th Amendment.

C. Command-and-Control Regulation

Regulation that specifies permissible and impermissible conduct through the adoption and enforcement of substantive standards is often called “command-and-control.” Although command-and-control regulation may be justified by reference to market imperfections of various sorts (e.g., lack of information), within its explicit scope it displaces rather than facilitates market transactions. Command-and-control regulation is often further divided into “design standards” that dictate structural or procedural details of private activities, and “performance standards” that set requirements for outcomes or outputs but allow them to be met using whatever method the regulated actor chooses.

Command-and-control regulators must also decide whether all activities of an industry or industrial sector should be subject to newly adopted or amended regulations, or whether the regulations should only apply to future products and production facilities (“grandfathering”). This decision is often a political one, but is sometimes linked to theories that emphasize the potential for regulation to force the development and dissemination of new technology.

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42 We take no position on whether such screening is, in fact, efficient, and whether it should be performed on all admitted patients, or just those that are high-risk. For a compendium of strategies to prevent HAIs, see 29 Infection Control & Hospital Epidemiology (Oct. 2008), available at http://www.journals.uchicago.edu/toc/iche/2008/29/s1. See also P. Wilton et al, Strategies to contain the emergence of antimicrobial resistance: a systematic review of effectiveness and cost-effectiveness, 7 Journal of Health Services Research and Policy 111 (2002).


See http://emergency.cdc.gov/stockpile/.
Command-and-control regulation requires a more extensive regulatory apparatus than other forms of government oversight. Legislatures generally delegate that responsibility to expert administrative bodies with rulemaking and/or adjudicative tools at their disposal. In health care, by contrast, self-regulation has been the predominant regulatory mechanism, based on widely held assumptions about the benefit to individual patients of medical expertise constrained only by professional ethics. Although these principles remain valid, an important question is whether medicine’s established self-regulatory capacity can deal effectively with a problem that was in large part caused by decades of deference to physician and hospital self-regulation (see Part III).

1. Design standards

Several forms of design standard are potentially applicable to reducing bacterial resistance to antibiotics. One possibility would be to “schedule” antibiotics as controlled substances through the federal Drug Enforcement Agency or a similar mechanism, and therefore limit antibiotic use by regulating dispensing by pharmacies. Under such a regime, older and narrow-spectrum antibiotics could be prescribed freely by health professionals who enjoy that privilege under state law, while newer, broad-spectrum drugs could only be prescribed by infectious-disease specialists and others who applied for and received a special permit, and who committed to filing paperwork documenting their decisions in particular cases. A few drugs might even be banned from private prescribing and held in reserve for emergency use on government order (with other regulation providing manufacturers with financial incentives to produce those drugs).

Similarly, the FDA could be given statutory authority to prohibit “off-label” prescribing of certain antibiotics, which would limit their use to the types of infections for which a New Drug Application had been approved. Much the same result would follow if the FDA manipulated other terms of drug approval. For example, if FDA only approved an injectable form of a particular antibiotic family, it would be prescribed much less frequently than would be the case if an oral formulation were available. Existing food and drug law would need to be amended for the FDA to “bank” a family of antibiotics in this way.

Another approach using design standards might specify the conditions under which each antibiotic, or any antibiotic, could lawfully be used. A regulatory body would list disease-causing organisms and/or sites and severities of infection, and would associate each with one or more allowed first-line therapeutic agents, procedures for granting exceptions, and prohibited treatments. Procedures for diagnosing bacterial infections and assessing sensitivity to particular antibiotics prior to treatment might also be required. Additional design standards could establish correct dosages, dosing schedules, and durations of therapy (unnecessarily prolonged exposure being a little-studied issue with considerable importance for the emergence of resistant strains). For very severe infections, monitored administration might be required, as is sometimes done for resistant tuberculosis today.

Infection control measures also can be instituted through design standards. Public health authorities could mandate screening newly admitted hospital patients for infection, and analogous requirements could be imposed on nursing homes, residential schools, and
other community institutions. Within those institutions, specific measures to maintain hygiene and prevent the spread of infection could be required as well.

If delegated self-regulation is deemed preferable to direct government control for some or all of these functions, design standards can specify the structures and processes for conducting that oversight. For example, accreditation requirements and survey-and-certification criteria for hospitals and health facilities might specify that infection control committees draft plans for preventing the spread of resistant bacteria, and that pharmacy and therapeutics committees design and enforce drug formularies that reduce antibiotic resistance.

Financial relationships between health care providers and the pharmaceutical industry that create conflicts of interest are a qualitatively different regulatory problem, whose nexus with antibiotic resistance is less clear. If deemed useful, such relationships are amenable to modification through design standards. For example, one could flatly prohibit payments or gifts by drug companies to physicians in connection with the treatment of infectious disease. Promotional activities could also be regulated, within the strictures imposed by the First Amendment.

2. Performance standards

Performance standards are an alternative to design specifications for most of the regulatory approaches discussed above. Although the design-performance dichotomy is not absolute, performance standards are generally framed in terms of measurable outcomes for patients, facilities, or communities rather than mandatory structures and processes. If a regulated entity failed to achieve those outcomes, one possible penalty for non-compliance would be to trigger a set of fall-back design standards that would be more effective, albeit costlier, for the entity to implement.

Performance standards for the prevention or spread of drug-resistant infections could be as simple as setting benchmarks for acceptable and unacceptable infection rates or antibiotic sensitivity profiles. As with medical outcome measures generally, standards of this type require that outcomes be ascertainable with statistical confidence. Similarly, the desired outcomes must be at least partially within the operational control of the regulated entity. Both of these preconditions favor application to hospitals, nursing homes, and large physician groups rather than small medical practices. Finally, fair comparison requires the development of valid risk- or severity-adjustment methodologies. There are various state and federal (Medicare) initiatives adopting this approach.44

Performance standards are also valuable where the controlling governmental body considers it practically or constitutionally preferable to delegate specific decisions to smaller political subdivisions or community coalitions. In clean air regulation, for example, the federal government requires states to develop and enforce implementation plans to reduce specified pollutants below threshold levels of risk. A similar approach might induce key stakeholders within communities, such as groups of hospitals and physician practices, to formulate joint plans for controlling antibiotic resistance.

Performance standards can induce problematic adaptive responses if regulated entities have discretion to choose which activities will be assessed. If hospitals are punished for

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44 See supra notes 11-12.
high infection rates, they will have an incentive to avoid more susceptible patients (e.g., those who are immunocompromised) – particularly if risk-adjustment is imperfect. Similarly, regulators must decide whether to demand similar levels of performance from all types of regulated institution. At the extreme, standards that reward improvement will have a very different impact than standards tied to an absolute level of performance.

3. New source standards

Substantive regulatory standards can be either implemented across the board or applied selectively to new technologies, services, or facilities. Existing practices are “grandfathered” for three main reasons: fairness (activities had been initiated without expectation of regulation), political support (incumbent firms prefer to selectively burden new entrants and thereby raise their rivals’ costs), and efficiency (new activities may create significant harm at the margin if a saturation point or threshold has been reached).

In some cases it may make sense to impose restrictions mainly on newer antibiotics to which resistance has not yet developed, while in other cases it may be preferable to restrict older drugs (particularly ones that are no longer in widespread use because of unpleasant side effects) in order to restore their potential utility. For health care facilities, it may be pragmatic to impose infection control requirements that depend on significant capital investment – such as isolation systems – only for new construction because of the high cost of retrofitting existing structures. This would be especially true if new facilities significantly expand high-risk clinical services and therefore opportunities for infections to develop or spread. On the other hand, applying regulation only to new construction creates perverse incentives for regulated entities to keep older, less well-designed facilities in operation longer.

“New source performance standards” are worth considering for antibiotics mainly because the principal mission of the federal Food and Drug Administration is to screen novel drugs and medical devices for lack of safety or effectiveness. With enabling legislation, FDA could use this authority to place conditions on approved indications for using new antibiotics, or to withhold approval from antibiotic molecules with sensitivity profiles no better than existing drugs that are likely to contribute to aggregate overuse or misuse. The former measure would be most effective if, unlike current FDA regulation but like the design standards discussed above, the agency’s determination limited actual use of antibiotics rather than merely prohibiting “off-label” marketing to physicians.

Analogously, FDA could selectively relax standards for, or expedite approval of, new vaccines, diagnostic tests or medical devices intended to improve infection control. This strategy is controversial, but it has been used in other areas where the perceived stakes are sufficiently high (i.e., AIDS) to justify overriding the general preference among FDA personnel for prioritizing safety over early access to untested medication.

4. Technology forcing


Substantive regulation can induce investment in new ways to reduce the risks of harm from existing activities if compliance depends on adopting technology that is not yet commercially available. Ambitious performance standards can “force” technologic advances by penalizing continuation of the status quo, while leaving to the regulated entities the manner in which the underlying problems are fixed. By contrast, design standards typically entrench existing technology that is known to be affordable, chilling rather than spurring innovation, and at most can mandate widespread application of technology that is currently used only by particularly wealthy or progressive entities.

With respect to antibiotic resistance, technology-forcing strategies are most likely to pay dividends for infection control practices in health care facilities, where advanced diagnostics, monitoring systems, and disinfectant methods can significantly reduce spread. Technology-forcing is probably less viable in office-based physician practices because of their limited financial resources, although it might be used to induce collective investment in health information technology.

D. Physical Rationing

Physical rationing represents highly intrusive government regulation, exceeded perhaps only by direct restriction of physical liberty such as quarantine.47 Although quarantines (and less Draconian measures such as “social distancing”) are legitimate and occasionally necessary public health measures to prevent the spread of disease, applying them to resistant infections would signal the failure of other regulatory measures and mark the triumph of the “superbugs.” Still, many of the possible interventions discussed in this article aim to improve priority-setting among uses and users of antibiotics in order both to promote long-term efficiency and to avoid manifest unfairness. Rationing merely does so explicitly and coercively.

Government generally plays a role in designing rationing systems for scarce resources when the price system that allocates and distributes most goods and services is deemed socially unacceptable. Rationing systems are typically made necessary by physical shortages, as for human organs for transplantation or, in wartime, for civilian access to materials the majority of which must be used for military purposes. In a market economy, rationing goods and services that can be produced for a price is rare because all markets clear. Occasionally, however, price controls necessitate rationing because demand at the capped price will inevitably exceed supply, and formal rationing systems are perceived by those backing them as fairer and/or less socially wasteful than informal alternatives.

Rationing can be implemented explicitly by rule, or implicitly through discretionary professional practices. Rationing schemes often have both allocative goals (ensuring that higher value uses get priority) and distributional goals (ensuring that everyone receives an acceptable amount). Unless allocation-oriented rationing can be governed by objective, scientific standards, attempts to set priorities through logical deliberation may provoke greater objection from the public than distributionally fair but seemingly random

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47 Some might object that physical rationing is indistinguishable in its effects from rationing by price, and so it should not be treated separately. Such objections ignore the history and rhetorical implications of the word “rationing” in common discourse. For better or worse, most people do not understand “rationing by price” to be rationing.
approaches such as lotteries and queuing. In socially contentious, constitutionally
delicate areas such as health, the details of rationing may be delegated to private self-
regulatory organizations (e.g., the United Network for Organ Sharing and affiliated
Organ Procurement Organizations) that are bound by professional ethics as well as by
explicit rules.

Rationing because of antibiotic resistance would likely be applied only in extreme
circumstances, such as managing a limited supply of effective drugs during an outbreak
of resistant disease. The U.S. government currently has a physical rationing plan for
dealing with pandemics.48 However, rationing principles are relevant to curbing overuse
and misuse of antibiotics generally. One can imagine giving particular hospitals or
nursing homes fixed budgets of particular drugs, which they would be responsible for
rationing among potential users. A rationing system for antibiotics would be contentious,
because medical criteria for which patients to treat first would inevitably blend scientific
and social judgments about clinical benefit.49 This concern has been ameliorated
somewhat for organ transplantation because prioritizing the sickest patients does not
seem to significantly disadvantage less sick individuals awaiting organs, and dialysis is
available to those waiting on the list.

Typically, rationing coupons are not tradable because exchange, while allocatively
efficient, undercuts the commitment to fairness and shared sacrifice that often motivates
public acceptance of rationing. However, as described briefly above with respect to
tradable permits, this concern might be outweighed for antibiotics by the potential for
exchange to motivate improvement in infection control and prevention at institutions that
can do so inexpensively, so that ultimately few if any patients end up being denied
medically necessary therapy.

III. Matching Regulatory Interventions to Institutional Capacity

In addition to being theoretically sound and appropriately designed, effective regulation
of antibiotic resistance must synchronize with existing laws and institutional capacities.
Regulatory institutions in the United States are embedded in a complex federal system
that divides authority both vertically between the federal government and states (and
localities), and horizontally among administrative agencies at each level. In addition, the
judicial branches of both federal and state government not only interpret legislative and
administrative enactments, but also create law while adjudicating private disputes that
can have systematic implications. These legal entities interact with a host of formal self-
regulatory organizations, self-governing private organizations, and social and
professional norms.

Failure to attend to institutional dynamics will doom any reform proposal, no matter how
well intentioned or rationally constructed. Accordingly, this section surveys the existing
regulatory framework, identifies factors that should be considered before attempting to

48 http://www.pandemicflu.gov/
49 Concerns about how “God Committees” were allocating access to dialysis led Congress to create
Medicare coverage for individuals with chronic renal failure, whether they qualified for Medicare or not.
See David Sanders & Jessie Dukeminier, Jr., Medical Advances and Legal Lag: Hemodialysis and Kidney
David Thoreau with bad kidneys.”)
implement reform through a particular institution or set of institutions, and suggests potentially productive areas of focus based on the foregoing analysis of regulatory goals and methods. Our goal is to provide a reasonably comprehensive listing of the institutions with which the problem of antibiotic resistance can be attacked, and the comparative advantages (and disadvantages) of doing so using each.

A. Federal government

Federal regulation has several functional characteristics relevant to addressing antibiotic resistance. One advantage of a national solution is that it helps limit interstate externalities when states might impose solutions that create internal benefits but increase external harms (e.g., tall smokestacks that send local pollutants into regional airsheds). Similarly, national solutions can reduce temptation by states to free-ride on other states’ regulation, potentially promoting a “race to the bottom.” Where regulation affects businesses that operate in many states, moreover, a uniform federal approach can reduce compliance and administrative costs, and is often more politically transparent and less subject to interest-group influence.

States vary in wealth and administrative sophistication. The federal government has far greater fiscal capacity than the states and fewer constraints on borrowing, which allows it to redistribute resources among states and to make long-term investments in things other than physical infrastructure. The rise of the federal administrative state since the 1930s, moreover, allows federal regulation to work comprehensively across industrial sectors, reducing “leakage” of harm into unregulated activities. Finally, federal regulation enjoys constitutional exclusivity in certain areas, such as negotiations with foreign nations and granting patent rights to inventors.

Federal regulation has disadvantages as well. Federal solutions are less attuned to local conditions. Federal authorities are remote, making enforcement difficult. Interventions often draw on federal fiscal capacity to the exclusion of other approaches, and regulatory design tends to be dictated by programs’ large aggregate budgetary implications. Finally, certain local activities are beyond the constitutional reach of federal law, and the federal government is constitutionally prohibited from commandeering (but not from purchasing) assistance from state authorities.

Several of these factors suggest a primary federal presence regulating antibiotic resistance. Resistance is fundamentally an externality problem, including internationally, making federal regulation attractive.\(^50\) The long time horizon over which benefits will become manifest, likely encompassing generations rather than lifetimes, argues for a large federal component, as the federal government is better equipped to incur costs today for distant improvements that can be estimated only with ample provision for scientific uncertainty. Synergies between control of infectious disease and the bioterrorism and emergency preparedness aspects of national security argue for a federal role as well, although problems can arise when subtle, complex scientific problems are assigned to agencies with highly visible, quasi-military missions.

\(^50\) We do not address global strategies in this paper, because the lack of centralized authority means that such strategies are more likely to be hortatory than regulatory. To be sure, the externalities from antibiotic resistance do not stop at national boundaries. Therefore, a role for global coordination undoubtedly exists.
Compared to state licensing of health professionals and facilities, federal involvement with health care providers and suppliers is indirect (except for the armed forces and veterans’ health) but nevertheless substantial, operating primarily through Medicare’s payment formulas and insurance coverage determinations. Large federal grants-in-aid for various state health and safety programs, investment in biomedical science, and supply-side incentives through patent law and FDA oversight also weigh on the side of federal intervention. In addition, federal tax law offers a national platform for incentivizing health care providers, insurers, and employers. Finally, through ERISA, the federal government can reach sources of private health coverage that are not subject to state insurance oversight, although this authority has not been exercised to influence clinical practice.

1. Medicare and Medicaid

The Medicare program, administered by the Center for Medicare and Medicaid Services (CMS), offers the longest lever for altering antibiotic usage and infection control patterns, primarily by refining its payment strategies or by amending its conditions of participation. Although Medicare’s beneficiaries account for only about 13% of the U.S. population, they account for a disproportionate percentage of spending on hospital and physician services. Medicare’s purchasing strategies can have a profound effect on the practice of medicine, and can create positive (and negative) spillovers that affect the care received by the rest of the population. Medicare’s influence over hospital practices is greater than its influence over physicians.

Medicaid is a state-administered health insurance program for low-income individuals, including the elderly, that is funded by both federal and state dollars (see state discussion below). Medicare exerts little direct oversight of long-term care facilities, which constitute a large reservoir of drug-resistant bacteria, but Medicaid pays for roughly half the nursing home care in the United States. States have considerable latitude to vary eligibility and benefits under Medicaid, but federal minimum standards must be met.

Medicare currently pays for care more or less regardless of its quality. By changing its payment system, Medicare more than any other program can create better global incentives to prevent infections, control their spread, and treat them appropriately. Medicare has recently taken tentative steps in this direction by identifying nosocomial infections for which it will not pay, including vascular catheter-associated infection, catheter-associated urinary tract infection, and certain surgical site infections. Although the total amounts at issue are modest, this approach marks a dramatic change in Medicare’s payment philosophy.

Alternatively, Medicare can identify certain infection control strategies that it believes should be used, and make the adoption of such strategies a “condition of participation” in Medicare. Once it does so, all providers who wish to contract with Medicare must adopt the specified practice. Historically, conditions of participation have focused on structural attributes of provider institutions, rather than details of clinical practice.

Priorities:

- Create financial incentives for hospitals to improve infection prevention and control
• Include specific infection-related practices in conditions of participation
• Expand reporting and disclosure for hospital infections

2. FDA

The FDA is a publicly visible watchdog for food and drug safety. It determines which drugs and medical devices may be sold in the United States. As part of the approval process, the FDA demands extensive information from drug and device developers on safety and efficacy. The FDA can specify the labeled uses for a drug or device, but it has essentially no control over how drugs or devices are actually prescribed by physicians once on the market. Unlike its substantive regulatory authority over drug sales, moreover, its ability to restrict marketing of off-label uses to physicians is limited by the First Amendment.

For approved drugs whose risks can be reduced by patient monitoring, the FDA can impose restrictions that affect how the product is distributed (the “RiskMAP” program).\(^51\)

Drugs currently subject to such restrictions include clozapine, thalidomide, lindane, and isotretinoin (Accutane). FDA also engages regularly in public education campaigns, and has already done so with respect to antibiotic overuse. It recently held hearings on antibiotic resistance,\(^52\) and its Center for Drug Evaluation and Research is the focal point for FDA activities with regard to the problem.\(^53\)

FDA can reduce inappropriate use of antibiotics by narrowing approved labeling or imposing conditions on distribution. However, the difficulty of obtaining FDA approval and the scope of approved uses affects the incentives of companies to develop, test, and market new drugs. As a result, FDA efforts to rationalize antibiotic use and improve long-term effectiveness of existing drugs are in tension with the desire to stimulate antibiotic development.

The FDA also regulates the amount of antibiotic residue that may be found in food products. However, a 2008 proposal to ban the use of cephalosporins in animal feed was withdrawn shortly before it was to go into effect.\(^54\)

The FDA model can be contrasted with that of the Drug Enforcement Agency (DEA), which enforces federal laws concerning controlled substances. To date, the DEA’s involvement with the practice of medicine has focused on the diversion and misuse of pain medication. Some of their efforts have been harshly criticized for targeting legitimate pain control practitioners. Although antibiotics have never been treated as controlled substances, the DEA presents a cautionary tale of the consequences if there are doubts as to the merits of a regulatory regime – particularly if it relies on the criminal law to achieve its ends.

Priorities:

• Work with drug makers to develop voluntary codes regarding antibiotic marketing


\(^{54}\) [http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm054431.htm](http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm054431.htm)
• Produce more extensive educational materials for physicians and patients
• Work with Department of Agriculture to reduce use of antibiotics in food production
• Seek authority from Congress to directly control uses of antibiotics and other drugs where uncontrolled use compromises effectiveness

3. National Institutes of Health

The National Institutes of Health (NIH) is the primary federal agency for performing and supporting biomedical research. NIH is composed of 27 Institutes and Centers, the most relevant of which to antibiotic resistance is the National Institute of Allergy and Infectious Disease (NIAID). NIAID receives a budget of roughly $4.2 billion per year, or roughly 15% of the total NIH budget. NIAID funds various grants and contracts to study antimicrobial resistance, including basic and translational research, and clinical trials.\(^{55}\) Concern has been raised that, in recent years, NIAID has been overly focused on research against bioterrorism, although NIAID representatives have asserted that additional funding for biodefense has complemented existing research work.\(^{56}\)

Priorities:
• Perform intramural research on antimicrobial resistance and infection control
• Refine resistance-related topics of interest for extramural research funding

4. Centers for Disease Control

The Centers for Disease Control (CDC) is the federal agency that identifies and addresses epidemics and outbreaks of infectious disease. Composed of six coordinating centers, it conducts epidemiologic investigations, and develops and implements disease prevention and control campaigns. CDC also provides assistance to other countries experiencing outbreaks of communicable diseases.

CDC is generally the lead-agency on federal drug-resistance initiatives, including the interagency task force on the problem.\(^{57}\) In this role, it defines the standards for identifying health-care-associated infections, and collects data from hospitals that participate in the National Healthcare Safety Network.\(^{58}\) At present, roughly 1,000 hospitals and outpatient dialysis centers voluntarily report outcome data on central line-associated blood-stream infections, surgical site infections, catheter-associated urinary tract infections, and pneumonia. CDC releases results as aggregate rates for different types of infections, and does not disclose hospital-specific information. Hospitals can risk-adjust their own results in order to see how they compare to other participating

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55 http://www3.niaid.nih.gov/topics/antimicrobialResistance/
hospitals. CDC also publishes guidelines for infection prevention and control, and maintains the strategic national stockpile of antibiotics and other medical supplies, to be used in the event of a public health emergency.

Priorities:
- Coordinate regional infection control and treatment practices
- Refine infection reporting systems for hospitals, with possible public disclosure
- Expand public education efforts
- Maintain strategic drug stockpiles

5. Agency for Healthcare Research and Quality
The Agency for Healthcare Research and Quality (AHRQ) is the lead federal agency for issues of health care quality. Its goals include encouraging safety and quality (by promoting delivery of the best possible health care), improving effectiveness (by encouraging the practice of evidence-based medicine), and increasing efficiency in the delivery of health care services. It has funded research into improving the use of antibiotics, issued reports describing ways of improving antibiotic usage, and sponsored educational campaigns aimed at physicians and patients regarding the problem of antibiotic resistance. AHRQ also sponsors the Healthcare Cost and Utilization Project, a compendium of health care databases. HCUP has been used to generate surveillance reports on antibiotic-resistant infections.

Priorities:
- Fund comparative effectiveness research on avoiding, controlling, and treating drug-resistant infections and control practices
- Develop national data sets on causes and consequences of antibiotic resistance

6. Public Health Service
The Public Health Service (PHS) is composed of a Commissioned Corps of more than 6,000 uniformed officers. PHS officers are health professionals who perform a wide variety of tasks and serve in many different settings, including direct provision of care to underserved communities and emergency response, including outbreaks of communicable diseases. Roughly half the PHS Commissioned Corps is assigned to the CDC.

Priorities:

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60 [http://emergency.cdc.gov/stockpile/](http://emergency.cdc.gov/stockpile/)


62 [http://www.hcup-us.ahrq.gov/overview.jsp](http://www.hcup-us.ahrq.gov/overview.jsp)

• Use PHS officers to assess antibiotic resistance patterns and associated infection control and treatment
• Work with local physicians and hospitals in PHS settings to coordinate and improve community practices

7. Veterans Health Administration

The Veterans Health Administration (VA) provides treatment for approximately 3.5 million military veterans through a network of hospitals and outpatient centers. After years of periodic scandals regarding quality of care, the VA made substantial improvements during the 1990s. Veterans generally remain in the VA system for many years, and care within the VA is more integrated than in much of the rest of the health care system. The VA can implement top-down strategies that are rarely available in private medical practice, such as strict limits on antibiotic usage and universal MRSA screening of patients admitted to specified clinical units.64

Priorities:
• Serve as pilot site for infection control innovations
• Serve as pilot site for health information technologies that monitor infection control and antibiotic use
• Develop systems to assess and address outpatient care practices and physician-hospital linkages
• Work with the Department of Defense (e.g., the Tricare program) on coordinated infection prevention and treatment practices for active duty military, military dependents, and veterans.

8. Patent law

The U.S. Constitution authorizes the issuance of patents to promote the progress of the “useful arts.” The U.S. Patent and Trademark Office issues patents to individuals or entities that invent or discover “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” The patent term is generally twenty years from the date of application. A patent confers the right to “exclude others from making, using, offering for sale, or selling” the invention in the United States or “importing” the invention into the United States. The patent holder is responsible for enforcing the patent. Both drugs and medical devices are routinely patented, although the usable term of the patent is much shorter than the statutory term after subtracting the time required to obtain FDA approval. As discussed above, patent law is a blunt instrument for making policy.

Priorities:
• Evaluate patent law changes to extend patent rights for narrowly marketed and used antibiotics

9. Internal Revenue Code
The tax system creates financial incentives that shape various aspects of the health care marketplace. A tax credit for expenditures on research and development induces companies to innovate. A tax exemption for nonprofit hospitals enables those institutions to provide community benefits. A tax exclusion for employment-based health coverage promotes risk-pooling through one’s employer and reduces sensitivity to rising medical costs. Because nonprofit hospitals play a central role in both breeding and controlling drug-resistant infections, tax law has the potential to increase private investment in improvement.

Priorities:
• Incorporate hospitals’ efforts to prevent and control community-based infections into IRS standards for reviewing charitable activities of tax-exempt organizations

10. Department of Labor
Pursuant to the Employee Retirement Income Security Act (ERISA), the Department of Labor (DOL) regulates employment-based health insurance. Employment-based coverage provides health insurance for roughly 60% of the U.S. population. ERISA distinguishes between employee benefit plans that are self-funded by sponsoring employers and those that are insured by commercial insurance companies. Self-funded plans are regulated solely by the DOL, while insured plans are regulated by both the DOL and state insurance commissioners.

Priorities:
• Interface with state insurance departments to examine the relationship between health benefit design and infection prevention and treatment practices

11. Office of Personnel Management
The Office of Personnel Management (OPM) is responsible for handling personnel arrangements for roughly 2.5 million federal employees. Through its administration of the Federal Employee Health Benefits Program, OPM can regulate the terms and conditions of the coverage made available to federal employees nationwide.

Priorities:
• Work with private health plans to improve benefit design and provider oversight regarding infection prevention and control

B. State and local government
State and local government interventions typically have strengths and weaknesses inverse to those discussed above for federal regulation. States tend to have closer connections to the problems they regulate, which allows them to adapt to local conditions and to improve both compliance and enforcement. New approaches to national problems can be tested in state “laboratories.” This diversity of approach, however, can produce large
disparities in outcomes across states, and may motivate a “race to the bottom.”

States are also limited in their ability to borrow, which increases pressure to cut spending in economic downturns. Because of the federal government’s fiscal advantages, state health insurance programs such as Medicaid and SCHIP are largely federally funded, and are subject to federal minimum requirements while otherwise being defined and administered at the state level.

Insofar as genes for antibiotic resistance and resistant bacteria themselves can spread nationally and often internationally, states and localities would not seem a good fit for the problem. On the other hand, resistant infections often cluster within particular health facilities, with bacterial agents continually reintroduced from reservoirs in surrounding communities. Successful initiatives by hospitals working together in cities or counties to curb infections suggests that some resistance may be associated with “germ-sheds” analogous to the watersheds routinely used to motivate and organize pollution control efforts.

State governments also possess specific advantages for regulating infectious disease. Infection control is a core function of state departments of public health, which have in place a comprehensive legal mandate, physical infrastructure, and professional workforce for disease prevention, surveillance, detection, evaluation, and treatment. States, not the federal government, set and enforce licensing requirements – including drug prescribing privileges – for physicians, nurses, pharmacists, and other health professionals. Similarly, states license and monitor hospitals, nursing homes, and other health facilities, often using periodic on-site inspections (called “survey and certification”). States also determine provider payment and benefit design for populations enrolled in Medicaid and SCHIP (children’s health insurance), accounting for large blocs of nursing home and obstetric care as well as substantial amounts of other health services. In addition, subsidized prescription drug programs for poorer residents give states significant influence over pharmaceutical practices. Finally, pursuant to the McCarran-Ferguson Act, states have primary regulatory authority over health insurance sold to state residents.

Priorities:

- Increase funding for state public health departments to develop, disseminate, and educate the public about infection prevention and control, including appropriate antibiotic use
- Focus state boards of medicine on educating physicians about antibiotic prescribing
- Develop and refine state department of health oversight of infection control in hospitals and other health care facilities, including public disclosure of reported infections
- Prioritize reducing infection risks in skilled nursing facilities as a state Medicaid initiative, perhaps with federal coordination and oversight
- Engage state insurance departments to work with one another and with the U.S. Department of Labor on health insurance benefit design to reduce resistant-infections

The empirical evidence on a race to the bottom is corporate governance is mixed; many scholars believe there is a “race to the top,” or a “race to nowhere in particular.” It is not obvious why a state would vie to have more antimicrobial resistance, since the costs would be disproportionately borne by its own citizens.
C. Self-regulation

Self-regulation by the medical profession has been the dominant mode of health system oversight for over a century. Federal and state health care regulation frequently occurs through or in conjunction with self-regulation, which has expanded beyond physicians to many other health care providers and suppliers. Self-regulation may be preferable to direct government control when technical expertise is required, cooperation from the regulated entities is important, or the regulated industry is undergoing rapid structural change. Self-regulation may be cheaper than direct regulation if its compliance costs are lower, and always appears less expensive to taxpayers because it is off-budget. On the other hand, self-regulation is often insular, self-serving, and anti-competitive.

Notwithstanding these risks, medicine has historically enjoyed wide latitude to self-regulate because of deference to physician expertise and trust in professional ethics and the charitable mission of non-profit hospitals. Even nominally governmental mechanisms, such as professional licensing boards, are routinely controlled (de facto, if not de jure) by the regulated entities or individuals. However, public demand for cost control has eroded these self-regulatory privileges to some degree in recent years.

Self-regulation takes various forms – all of which may have potential for attacking the problem of antibiotic resistance. Certification or accreditation systems can be used to implement information disclosure requirements or substantive design and performance standards relating to infection control and antibiotic use. A self-regulatory imprimatur is typically used to convey information about superior quality or reliability to a purchaser, but can become a de facto minimum quality standard. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), for example, reviews hospital compliance with a host of structural and process measures of quality, and conducts periodic direct inspections. American hospitals are nearly universally accredited because JCAHO review serves to verify compliance with federal conditions of participation in Medicare and Medicaid. Similar JCAHO reviews occur for nursing homes, ambulatory surgical centers, and other health facilities, while managed care organizations undergo accreditation from the National Committee on Quality Assurance and other groups.

State licensing is necessary but not sufficient for modern medical practice. Advanced health professional certification operates through a parallel system of self-regulatory organizations, and focuses more on past training than on current practice environment or processes of care. Most U.S. physicians have specialty training, with credentials issued by medical specialty boards following examination, which occurs after completion of graduate programs that themselves are accredited by residency review committees. Additional certifications are available from a variety of organizations, and attest to particular skills or education. Unlike medical licensure, none of these credentials have formal legal status, but physicians who lack them may find it more difficult to secure admitting or procedural privileges in hospitals, and to obtain contracts from managed care organizations. Other health professionals and public health professionals have similar self-regulatory mechanisms in place.

Each of these mechanisms may be useful in reorienting health professional education toward proper use and stewardship of antibiotics. These mechanisms can also be used to improve infection control, both generally and for the purpose of designating specially trained individuals to whom use of the most powerful antibiotics might be entrusted.
Clinical practice guidelines are another common self-regulatory approach potentially adaptable to reducing antibiotic resistance. Traditions of physician autonomy and customized treatment were long considered incompatible with prescriptive approaches to medical management. However, research demonstrating unexplained (and almost certainly unwarranted) practice variation, coupled with pressure for cost containment, has greatly increased interest in guidelines. Guidelines are rarely mandatory, but are influential with patients, insurers, and policymakers. Because competing guidelines are issued by generalist physicians, competing specialists, and insurance groups, even guided practice is strikingly variable. Several well-respected entities have constructed guidelines (or issued reports similar to guidelines) that bear on antibiotic resistance, including the Institute of Medicine (IOM) of the National Academies of Science, the Leapfrog Group, the National Quality Forum, and the Institute for Healthcare Improvement.

Most recently, three epidemiological societies joined with the American Hospital Association and JCAHO to issue a compendium of guidelines on ways to prevent infection. JCAHO also has several infection control initiatives, including performing a root cause analysis of infection control related sentinel events, encouraging hand-washing, and preparing a compendium of strategies to prevent hospital-acquired infections.

Self-regulation often operates locally as well, with internal monitoring and compliance systems either being self-imposed or expressly required by government. Acute care hospitals are the most common sites for internal self-regulation, much of which is essentially made mandatory by JCAHO accreditation standards.

Physicians undergo strict initial and periodic review in order to gain the right to admit patients to a given hospital, thereby joining the “medical staff.” Hospitals have internal oversight committees, composed of medical staff physicians and other expert professionals, to deal with avoidable morbidity and mortality, surgical facilities, infection control, and drug therapies – all of which have responsibility for areas that implicate antibiotic resistance. A secular trend away from “open” medical staffs (independent physicians practicing at several hospitals concurrently) and toward exclusive relationships between physicians and community hospitals, along with the emergence of “hospitalists” (who limit their practices to hospitalized patients and do not maintain private offices) is likely to increase the potential effectiveness of these institutional compliance systems over time.

Professional norms that influence rates of medical error have already begun to change, particularly for low-technology interventions such as proper patient identification. For

67 http://www.leapfroggroup.org/
68 http://www.qualityforum.org/
69 www.ihi.org
71 ref=us
73 http://www.jointcommission.org/PatientSafety/InfectionControl/hh_monograph.htm
example, norms regarding hand-washing, use of sterile barriers for intravenous line placement, and care of indwelling catheters are all important to reducing resistant infections. Other relevant norms are connected more to medical ethics than to microbiology. Notably, contemporary ethics that orient physicians only to the immediate benefit of the individual patient under their direct care may need to be modified, if not superseded, by norms of population health management and stewardship of scarce resources.

Consumers and patients seldom have a direct voice in medical self-regulatory organizations, although they may be entitled to representation. Nonetheless, consumer and public interest groups can be important catalysts in addressing the problem of antibiotic resistance. Consumer groups that have issued statements or position papers on the problem of antibiotic resistance include Consumers Union,\(^\text{74}\) the Center for Science in the Public Interest,\(^\text{75}\) and the Committee to Reduce Infection Deaths.\(^\text{76}\)

### D. Private tort litigation

In the United States, health care oversight is accomplished by an ad hoc mixture of “public law” (e.g., the Medicare program) and “private law” (litigation over contractual agreements or personal injury). Medical malpractice litigation is highly salient to American physicians, and therefore bears discussion in connection with alterations of their clinical practices. Product liability lawsuits are equally important to makers of drugs, medical devices, vaccines, and diagnostic tests.

Private tort litigation, under state law and generally in state court, might be initiated by individuals seeking compensation for negligent treatment (e.g., failure to protect the patient from a drug-resistant infection and/or failure to adequately treat that infection). Injured plaintiffs can recover both economic damages (lost earnings and cost of subsequent medical treatment) and non-economic damages (pain and suffering). In theory, the obligation to compensate injured plaintiffs deters defendants from providing negligent treatment in the first place.

Lawsuits against corporations such as pharmaceutical manufacturers are governed by similar standards, although punitive damage awards are more common than in claims involving individual physicians or hospitals. Although the law continues to evolve, drug makers can be sued for negligence even when a product has received FDA approval. Vaccine manufacturers are protected from litigation by the National Childhood Vaccine Injury Compensation Act of 1988; before filing suit, persons injured by vaccines must seek no-fault administrative compensation through the Department of Health and Human Services, the Department of Justice, and the U.S. Court of Federal Claims.

Courts labor under significant institutional constraints that hinder their ability to effectively address the problem of antibiotic resistance.\(^\text{77}\) Although some plaintiff

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\(^{77}\) Pamela Nolan, Unclean Hands: Holding Hospitals Responsible for Hospital-Acquired Infections, 34
lawyers advertised for clients injured by hospital-acquired infections,\textsuperscript{78} and there have been some extremely large verdicts in cases involving MRSA infection,\textsuperscript{79} relatively few lawsuits have been brought against health care providers despite considerable publicity and large numbers of affected patients. As a result, the cases that courts encounter are likely unrepresentative of the larger pool of injuries.

For a case to be brought, an aggrieved patient must find a lawyer willing to take the case. Many of those injured by drug-resistant infections are elderly – resulting in lower damages, particularly in states with damages caps.\textsuperscript{80} Most cases also raise difficult issues of causation and standard of care, including proving that a particular defendant is responsible for a particular infection. Tort cases are brought before non-specialty courts, who view each case and the range of acceptable remedies in isolation. Defendants are often willing to pay more for a confidential settlement, which means that other injured persons and other health care providers may not receive information about risks and injuries.\textsuperscript{81} Finally, the transaction costs of resolving disputes through the tort system are extremely high.

V. Conclusion

Profligate use of antibiotics over the past several decades has created risks of resistant infection that affect everyone. No magic medical bullet exists to eradicate these risks; neither is there a magic regulatory bullet. Still, judicious regulation can help ensure that antibiotics are reserved for circumstances where they are needed, and that the most appropriate treatment is provided. The optimal regulatory strategy is multi-pronged, and each aspect will undoubtedly be controversial. Whatever regulatory strategy is pursued, it must synchronize with current and future institutional capacity for it to work effectively. Otherwise, it will be very difficult to implement, and equally difficult to make the numerous ongoing adjustments that will be necessary. Should that occur, we will soon experience a real tragedy of the commons.

\textsuperscript{78} http://www.kcrlegal.com/legalspecialties/medicalmalpractice/hospital-infections.asp
\textsuperscript{81} Jack Dolan and Dave Altimari, Court Order Silences Victims: Hospital Sues over Families’ Comments, Hartford Courant, July 26, 2002.