VALUE-BASED MANDATED HEALTH BENEFITS

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Mandated health benefit laws figure prominently in health reform debates. These laws, which are primarily enacted by the states, require health insurers to cover specific medical treatment, services, or supplies such as mental health treatment, mammograms, or diabetes testing supplies. Critics argue that mandated health benefit laws increase health insurance costs, decrease consumer choice, and often are the product of rent-seeking, rather than sound public policy. This Article seeks to further the discussion of mandated health benefit laws by systemically identifying permissible rationales for such laws. The justifications identified include addressing (1) market failure that leads to non-availability of coverage, (2) suboptimal utilization of a medical treatment or service, (3) undesired insurance company coverage determinations, (4) cognitive shortcuts and biases, and (5) failures in the group market. For any of these justifications to be used, however, there must also be a viable justice claim for such coverage or the coverage must have a positive cost-benefit or cost-efficiency analysis compared to non-coverage. This Article argues that being precise about the justification for a mandated health benefit law allows such a law to be precisely tailored to solving the problem which justifies its existence. These tailored mandates, referred to as value-based mandates, continue to advance the important policy goals of mandates, while being significantly more efficient than non-value-based mandates. The Article concludes with three case studies of existing mandated benefit laws, analyzing each under the value-based framework set forth in the first part of the Article.

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INTRODUCTION

Mandated health benefit laws figure prominently in health reform debates. These laws, which are primarily enacted by the states, require health insurers to cover specific medical treatments or services such as mental health treatment or diabetes testing supplies. Mandated benefit laws figure prominently in health reform debates because they present a fundamental tension in our health care system: the desire to keep costs low versus the desire to spread the risk of loss as widely as possible. Critics of these laws are concerned with both the premium cost increases that can result and the limits on choice they place on consumers in the health insurance marketplace. In addition, commentators express deep concerns that economic rent-seeking by special interest groups, rather than sound health policy, drives these laws.

I have argued elsewhere that mandated health benefit laws serve an important policy function by allowing certain health risks to be widely pooled, and should therefore be retained as an important health policy tool.[1] This Article furthers the discussion of mandated health benefit laws by (1) systematically identifying permissible justifications for mandated health benefit laws and (2) proposing that such laws be specifically tailored to remedy the problem they are aimed at alleviating. The need for such tailoring may seem obvious, but mandates to date typically have not been so tailored. Instead, such laws have been passed in the form of blunt coverage mandates (for example, a requirement that all health insurance contracts cover "mental health treatment"). For example, if some smoking cessation products or programs are demonstrably more effective than others, a blunt mandate to cover all smoking cessation treatments and services would be undesirable. A more desirable type of mandated benefit law would cover only those smoking cessation treatments that have been established to be the most clinically effective. I refer to this type of finely tailored law as a value-based mandated health benefit.

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1. *See generally* Amy B. Monahan, *Federalism, Federal Regulation, or Free Market? An Examination of Mandated Health Benefit Reform*, 2007 U. ILL. L. REV. 1361 (2007). In that article, I addressed the disparate applicability of mandated benefit laws to insured versus self-insured plans under the Employee Retirement Income Security Act of 1974 (ERISA). As a result, this Article leaves aside the issue of such disparate regulation.

This proposal to target mandated benefit laws is important not just for meaningful reform of these laws, but also for health reform generally. Limited resources constrain our health care system, and the United States has yet to develop a method of rationing health care that is both effective and acceptable to consumers. Clinical effectiveness data now exist that were not available forty years ago when mandated benefit laws became widespread, and these data allow policy makers to be more precise in structuring mandates to efficiently achieve policy goals. Embracing value-based coverage terms with respect to mandated benefit laws is a good place to start, and provides a good test case for embracing value-based medicine more broadly. This experiment will allow us to determine if value-based coverage provisions are as effective as the data suggest, what line drawing problems exist, the acceptability of such limits for both doctors and patients, and how effective an appeals process will be. In the short term, mandated benefit laws will be improved, and in the longer term we will learn more about a promising rationing tool for health care generally.

This Article begins by identifying permissible rationales for mandating that an insurance contract, which does not otherwise cover a given benefit, should be required by law to do so. The justifications identified include addressing (1) market failure that leads to non-availability of coverage, (2) suboptimal utilization of a medical treatment or service, (3) undesired insurance company coverage determinations, (4) cognitive shortcuts and biases, and (5) failures in the group market. For any of these justifications to be used, however, there must also be a viable justice claim for such coverage or the coverage must have a positive cost-benefit or cost-efficiency analysis compared to non-coverage. Being precise in identifying the rationale for a mandate is critical to the second step of the value-based process—tailoring the mandate to the specific goal we are trying to achieve.

In order to illustrate the proposed value-based process, the second part of this Article provides three case studies of existing mandated benefit laws: infertility treatment, diabetes, and high dose chemotherapy/autologous bone marrow transplant (HDC/ABMT) for breast cancer. The infertility case study is the most extensively analyzed of the three case studies due to its unique complexity. It provides an example of a benefit that appears to be well justified, but which needs to be tailored in

order to limit negative health outcomes for mothers and their children.

The diabetes case study illustrates how a very common mandate could be improved to better target changes in patient behavior. The primary goal of a diabetes mandate is to increase patient compliance with doctors' orders regarding at-home blood glucose monitoring (referred to as self-monitoring). There is evidence that participating in diabetes education can increase self-monitoring behavior, and also that self-monitoring increases as the price of such monitoring decreases. As a result, a diabetes mandate might be much more effective if it was tailored to specify both that diabetes education and self-monitoring supplies must be covered, and that health insurance plans may not apply deductibles or copayments to such coverage. Doing so should not only improve health outcomes for diabetics, but also be cost-effective.

Finally, the brief HDC/ABMT case study provides an example of a politically popular mandate that never should have been adopted. There simply is not sound clinical data that HDC/ABMT is superior to traditional methods of breast cancer treatment, yet it comes at significantly increased cost and harms ongoing clinical trials.

Value-based mandates can improve health outcomes and help to ensure that our medical dollars are spent effectively. Because mandates require the insured population to share the risk of loss associated with certain conditions, the involuntarily pooled premiums should be spent wisely. Coverage provisions should be structured to effectively address the problem that occurs in the unregulated market, and in many cases the data is now available to do so effectively. Mandates are a good place to start embracing value-based coverage provisions and, while there may be political opposition to such targeting, this Article argues that we should do so. Adopting a system of value-based mandates will operate as a kind of pilot project to determine whether value-based coverage provisions actually deliver the value promised, whether they are politically acceptable, and how well they function in practice.

I. ON WHAT BASIS SHOULD WE MANDATE COVERAGE OF SPECIFIC SERVICES?

Most privately-financed health insurance contracts in the United States cover a broad range of treatments and services,

provided such treatments and services are both medically necessary and non-experimental.[2] Even with this seemingly broad coverage, many treatments and services remain excluded. Some services are specifically excluded under the contract terms, in some instances even though they are both medically necessary and non-experimental. For example, dental care, in vitro fertilization, and treatment for morbid obesity are all common contractual exclusions.[3] In addition, insurance companies deny coverage for some services and treatments based on a determination that they are not medically necessary (even where the treating physician believes that they are) or that they are experimental. For example, autologous bone marrow transplants for breast cancer patients were, for many years, not covered by many insurance companies on the basis that such treatment remained experimental.[4]

This Part seeks to identify the circumstances under which the state is justified in interfering with freedom to contract principles by mandating that all health insurance contracts provide coverage for certain medical treatments and services. The Part will begin with a brief background on health insurance contracts, and will then analyze five market problems, each of which provides initial justification for modifying the standard health insurance contract by requiring specific coverage provisions. Identifying a specific justification for a mandate and ensuring that the necessary conditions to rely on such justification are satisfied is critical for formulating a value-based mandate. The Part concludes with a discussion of the two overriding necessary conditions for all mandates: either a valid justice claim or a positive cost-benefit or cost-efficiency analysis.

A. Brief Background on Health Insurance Contracts

Health insurance contracts in the United States, while differing in many respects, have substantially similar coverage terms.[5] As noted above, nearly all such contracts condition coverage of a given service on such service being "medically

2. *See* CLARK C. HAVIGHURST, HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM 117–37 (1995).

3. *See id.* at 141 n.19.

4. *See* Peter D. Jacobson et al., *Litigating the Science of Breast Cancer Treatment*, 32 J. HEALTH POL., POL'Y & L. 785, 786–87 (2007).

5. *See* HAVIGHURST, *supra* note 2, at 117–37.

necessary."[6] In addition, nearly all such contracts exclude or limit coverage of "experimental" treatments.[7] One study found that of the "relatively comprehensive contracts" reviewed, all of them excluded the following: "dental care, sexual reassignment surgery, in vitro fertilization, reversal of voluntary sterilization, treatment for morbid obesity, and cosmetic surgery undertaken solely for purposes of beautification."[8] Other explicit exclusions vary significantly from contract to contract.[9]

Before examining in detail the possible justifications for requiring coverage of specific services in all health insurance contracts, it is necessary to explicitly state an important assumption. In discussing possible justifications for requiring that a specific benefit be covered by every contract of health insurance, this Article assumes that the benefit is either (1) one that is not included in a standard health insurance contract[10] or (2) one for which coverage is routinely denied as either not medically necessary or experimental in nature. There obviously is no need to mandate a benefit that is included in the standard health insurance contract. Mandates should only be considered for benefits that are routinely excluded from the standard terms of health insurance coverage by prevailing market forces or routinely denied under medical necessity or experimental standards.

The Subpart below identifies the problems that potentially justify market intervention and the necessary conditions that must be satisfied to rely on such justifications. The Supbart then discusses justice and cost-effectiveness concerns, which are relevant for all possible mandates.

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6. *Id.* at 125. Plans do differ in how they define medical necessity. *See id.* at 125–26.

7. *Id.* at 132–33.

8. *Id.* at 141 n.19.

9. *See id.* at 141.

10. Of course, there is no national "standard health insurance contract." Health insurance contracts can take many different forms, although major carriers do have standard coverage terms and these terms tend to be fairly consistent from carrier to carrier. *See id.* For purposes of simplicity, I will assume that the vast majority of health insurance contracts contain the same standard terms.

B. Market Flaws Providing Initial Justification for Mandated Benefit Laws

1. Market Failure That Leads to Nonavailability of Coverage

For certain conditions, market failure exists that effectively limits the availability of insurance coverage for such conditions. Mandated benefit laws are often justified in order to address this market failure, in particular to preserve the risk-pooling function of insurance. In order to understand the risk-spreading function of mandated benefit laws, it is first necessary to understand the process of purchasing insurance. There are two basic decisions that must be made by an individual considering health insurance coverage: (1) whether or not to purchase such coverage at all and (2) the scope of such coverage. I refer to the first decision, the overall purchasing decision, as the macro-level decision, and the second decision, regarding the scope of coverage, as a micro-level decision. Adverse selection is thought to affect both types of decisions.

Adverse selection has been defined as "the process by which insureds utilize private knowledge of their own riskiness when deciding to buy or forgo insurance."[11] In the health insurance context, the purchaser often has more information about his or her risk than does the insurance company.[12] With respect to the macro-level purchasing decision, the theory of adverse selection posits that, at the same price level, those who are at higher risk will buy more generous insurance than those who are at lower risk.[13] Insurance companies can lose money under this scenario when only those who represent above-average risks choose to purchase insurance.[14] As this process of adverse selection occurs, insurance companies must adjust their premiums upward in order to reflect the greater-than-average risk pool.[15] As prices rise, the individuals that will

11. Peter Siegelman, *Adverse Selection in Insurance Markets: An Exaggerated Threat*, 113 YALE L.J. 1223, 1223 (2004).

12. This phenomenon is referred to as "information asymmetry." *See id.* at 1223–24.

13. *See* David M. Cutler & Richard J. Zeckhauser, *The Anatomy of Health Insurance*, *in* HANDBOOK OF HEALTH ECONOMICS 563, 607 (Anthony J. Culyer & Joseph P. Newhouse eds., 2000).

14. Siegelman, *supra* note 11, at 1224 (assuming that the product is priced at average risk levels).

15. *See* Cutler & Zeckhauser, *supra* note 13, at 607.

find insurance purchase attractive will be relatively higher-risk individuals. The price of premiums will continue to rise, as will the risk level of the individuals who elect to purchase insurance. The result can be a "death spiral" where premiums rise to a level where insurance is no longer effectively available.[16]

Adverse selection also occurs at the micro-level; that is, it affects a purchaser's decisions with respect to which benefits he or she wants included in his or her health insurance policy. Health insurance providers offer a standard menu of benefits that covers certain treatments and services and excludes others.[17] If a purchaser desires coverage that is excluded under the standard contract, he or she may request a rider to the standard contract covering the desired benefit.[18] Requesting such a rider signals to the insurance company that the individual knows or has reason to know that he or she will likely use such services. In this way, excluding the benefit from the standard contract helps the insurance company overcome the information asymmetry that is otherwise present and therefore defeat the adverse selection problem. With this new information, the insurance company prices the rider accordingly, at or near the expected cost of benefits (plus administrative expenses). The rider is no longer attractive to the would-be purchaser because of the high price, and the rider is not purchased.[19] To be clear, this is a desirable result from the insurance company's perspective. At a very limited cost, the insurance company has been able to gain valuable information

16. Siegelman, *supra* note 11, at 1224; *see also* Seth J. Chandler, *Visualizing Adverse Selection: An Economic Approach to the Law of Insurance Underwriting*, 8 CONN. INS. L.J. 435, 436 (2002) (explaining that insurance price increases drive lower-risk individuals out of the market).

17. Health care contracts are obligationally incomplete. Russell Korobkin, *The Efficiency of Managed Care "Patient Protection" Laws: Incomplete Contracts, Bounded Rationality, and Market Failure*, 85 CORNELL L. REV. 1, 29 (1999). While the purchaser's obligations are fully specified, the insurance company's obligations are not, due to the intricacies of health care. *Id.* It would be very difficult to draft a health insurance contract that fully specified coverage terms for every possible health situation. *Id.*

18. In practice, the availability of riders may be quite limited, at least for individual purchasers. While there is little study of the subject, an informal look at individual insurance policies conducted by the author reveals that a small number of riders are made available to purchasers. These tend to be riders covering maternity, prescription drug, dental, and preventive services.

19. It is possible, of course, that an individual is so confident of utilization that she will purchase the rider, even if it equals the expected cost of treatment. This might be done, for instance, as a pre-commitment device to force the individual to set aside the money for the treatment. However, a rider that essentially functions as a pre-paid services contract is not insurance.

about expected utilization of a given benefit and price it accordingly. From the purchaser's perspective, the result is undesirable because it effectively precludes insurance coverage for certain conditions or treatments. There is, therefore, little to no risk pooling associated with the condition because risk is spread only among those who are expected to utilize coverage for the condition, not among the population as a whole. The result is that insurance coverage for the condition at issue ceases to be effectively available. Even if the rider is available and purchased, it does not function as insurance but rather as the pre-payment of expected medical expenses.

Mandating coverage of certain services solves the micro-level adverse selection problem for purchasers by eliminating the need for purchasers to signal their risk of incurring certain losses.[20] Mandated benefit laws therefore preserve information asymmetry at the micro level, requiring that these micro-level risks be spread across the entire insured population, rather than only spreading the cost among affected individuals. The result is that all insured individuals must pay slightly higher premiums to cover the mandated benefit, but affected individuals will not be priced out of such coverage. In essence, mandated benefits mandate risk spreading for certain treatments.[21]

On this theory, using adverse selection as a justification for mandating the inclusion of specific benefits in every health insurance contract requires evidence that (1) the benefit is one that individuals often know or have reason to suspect they will utilize during the contract term and (2) the likelihood of utilization is not easily or cost-effectively discovered by the insurance company. If the benefit relates to a condition that does not meet such requirements, risk spreading could not be used as justification for interfering with the market.[22]

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20. When coverage of a particular service is mandated, the purchaser no longer needs to request a rider for such coverage and, therefore, can avoid signaling risk to the insurance company.

21. The risk is spread only among the state insured population. *See* KAISER FAMILY FOUNDATION & HEALTH RESEARCH AND EDUCATIONAL TRUST, EMPLOYER HEALTH BENEFITS 2007 ANNUAL SURVEY 146, *available at* http://www.kff.org/insurance/7672/upload/76723.pdf. This excludes a significant number of individuals who receive coverage through an employer that self-insures its health benefits. *See id.* Approximately fifty-five percent of workers with employer-provided health coverage are covered by a self-insured plan. *Id.* at 147 ex.10.1.

22. An unknown, which I do not address in this Article, is whether mandating coverage for a treatment that is excluded from a standard health insurance contract, but for which individuals have no private knowledge concerning utilization, can be justified on a risk-spreading basis. Theoretically, this should not be prob-

2. Suboptimal Utilization of a Medical Treatment or Service

Health insurance mandates may be used to increase utilization of a particular treatment or service. Utilization can be increased as follows: including a treatment or service in a health insurance contract lowers the price associated with receiving such treatment or service.[23] Standard economic theory holds that demand for price-elastic services will rise as prices fall. Therefore, mandating that all health insurance contracts cover a treatment or service raises the possibility of increasing demand, and therefore utilization, of such service.

Whether or not a mandated benefit law will increase utilization rates for the service at issue, and whether such increase is desirable from a policy perspective, depends on a number of factors. With respect to the effect on utilization rates, we would expect to see an increase only if demand for the service at issue is price elastic. A medical service is price elastic when the quantity of the service that is demanded varies markedly and inversely with price.[24] There is evidence that medical care, generally speaking, is price elastic.[25] Outpatient services have been found to be more price elastic than inpatient services,[26] but relatively little evidence is available regarding the price elasticity of specific treatments.[27] Unfortunately, more than one study has found that the price elasticity of medical services

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lematic in a functioning market. If there is no private information concerning utilization and an individual requests a rider, the price of the rider should reflect the community-level risk. However, I was unable to find any studies of this aspect of the insurance market to confirm that the market does, in fact, price these riders at community-level risk. As a result, I leave this issue aside.

23. This assumes, of course, that any deductible under the plan has first been satisfied. For simplicity, I will assume that either no deductible applies to the service, or the deductible has been satisfied. While this is not always true in the real world, it is also possible to specify in the mandated benefit requirement that the service may not be made subject to any deductible. *See, e.g.*, 40 PA. STAT. ANN. §§ 3501–3508 (West 1999) (exempting mandated coverage of childhood immunizations from any otherwise applicable deductible).

24. Karen Davis, *Consumer-Directed Health Care: Will It Improve Health System Performance?*, 39 HEALTH SERVICES RES. 1219, 1220 (2004).

25. *See* Willard G. Manning et al., *Health Insurance and the Demand for Medical Care: Evidence from a Randomized Experiment*, 77 AM. ECON. REV. 251, 251 (1987).

26. *See id.* at 258.

27. *See* Cutler & Zeckhauser, *supra* note 13, at 580–84 (summarizing available studies regarding price elasticity of medical services).

does not vary based on the clinical effectiveness of the treatment.[28]

A remaining question is when, if ever, the government should seek to increase demand for a given medical service through a mandated benefit law. It does not make sense, on this justification, to mandate a benefit with respect to which there is already "optimal" utilization. Rather, a mandate would be justified where there is evidence of suboptimal utilization. Such suboptimal utilization could result from externalities associated with the treatment or inefficient use of alternatives that result in poorer health outcomes, higher prices, or both. Two necessary conditions therefore must be satisfied before mandating coverage for a particular treatment in order to increase utilization of that treatment: (1) evidence of suboptimal utilization of the treatment and (2) evidence that such treatment is sufficiently price elastic such that reducing the cost for such treatment will increase its utilization to near-optimal levels.[29]

3. Undesired Insurance Company Coverage Determinations

As previously discussed, most insurance contracts cover all "medically necessary" services, subject to certain categorical

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28. *See* Kathleen N. Lohr et al., *Use of Medical Care in the RAND Health Insurance Experiment*, 24 MED. CARE S1, S31–38 (1986) (finding that cost sharing was generally just as likely to lower use when care is thought to be highly effective as when it is thought to be only rarely effective); Amal N. Trivedi et al., *Effect of Cost Sharing on Screening Mammography in Medicare Health Plans*, 358 NEW ENG. J. MED. 375, 377–78 (2008) (finding that cost sharing decreased mammography screening rates among women who should undergo screening according to accepted clinical guidelines); *see also* Susan Bartlett Foote & Robert J. Town, *Implementing Evidence-Based Medicine Through Medicare Coverage Decisions*, 26 HEALTH AFF. 1634 (2007) (identifying a lack of evidence-based medical utilization).

29. I am somewhat tempted to include a third necessary condition, which is an effective means of mitigating moral hazard. Having insurance coverage against loss can create so-called moral hazard, where the insured individual becomes more likely to incur a loss than he or she would be in the absence of insurance. *See* THOMAS RICE, THE ECONOMICS OF HEALTH RECONSIDERED 82 (1998). The basic idea is that if you do not bear the cost of the loss, you are less likely to seek to prevent it. Here we are trying to increase utilization levels, but not above the optimal level. In other words, we only want to increase utilization among a target population. We may need to have a mechanism in place to prevent a utilization increase outside of our target population. As will be discussed later, one of the benefits of value-based mandates is that they can be structured to mitigate against moral hazard.

exclusions.[30] In addition, most contracts exclude, or place limits on, treatments deemed experimental.[31] When insurance companies deny coverage for treatments based on the medical necessity or experimental limitations, the result can be politically unpopular or may reflect bad health policy. Governments can redress such undesired outcomes by mandating coverage for the treatment at issue.[32]

This justification for regulating the substance of health insurance contracts is perhaps the most troubling. Let us take first the case of mandating coverage for a treatment frequently denied based on a lack of medical necessity where such denials are politically unpopular. In the 1990s, media gave considerable attention to health maintenance organizations' (HMOs) and insurers' policies of discharging women and infants from the hospital within twenty-four hours of childbirth.[33] Insurers and HMOs had begun limiting post-partum stays to twenty-four hours on the basis that longer stays were not medically necessary.[34] Despite the fact that there was no study demonstrating any "statistically significant increase in infant or maternal mortality after a rapid postpartum discharge,"[35] Congress passed the Newborns' and Mothers' Health Protection Act of 1996, requiring insurers to cover a minimum postpartum stay of forty-eight hours, or ninety-six hours in the case of a delivery by caesarian section.[36] By most accounts, this legislation was anecdote driven and a political response to insurance companies being seen as unkind to child-bearing women and infants.[37] Given our limited health care resources, requiring coverage of a particular service solely because of the political unpopularity of insurance company denials should not be tolerated.[38]

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30. *See* HAVIGHURST, *supra* note 2, at 117–37.

31. *Id.* at 132–33.

32. Arguably, this is what occurred with the Newborns' and Mothers' Health Protection Act of 1996. *See generally* David A. Hyman, *Drive-Through Deliveries: Is "Consumer Protection" Just What the Doctor Ordered?*, 78 N.C. L. REV. 5 (1999) (examining legislation mandating coverage of a minimum postpartum hospital stay).

33. *See id.* at 18–20.

34. *Id.* at 42.

35. *Id.* at 45.

36. 42 U.S.C. § 300gg-4 (2000).

37. *See, e.g.*, Hyman, *supra* note 32, at 84–87.

38. Ordinary citizens are not great arbiters of these types of medical decisions because they lack technical expertise. *See* MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS, AND ECONOMICS OF RATIONING MECHANISMS 93 (1997).

The second case, mandating coverage to materially improve health outcomes, is significantly different. Let us stay with the example of mandating hospital stays following childbirth, but assume slightly different facts. Let us assume that many insurance companies were covering hospital stays of only twenty-four hours following childbirth. Let us further assume that based on sound scientific study, health policy experts had concluded that hospital stays of only twenty-four hours following childbirth significantly increased maternal and child morbidity and mortality. Under those circumstances, a mandate to cover longer post-childbirth hospital stays could be warranted.

One might object at this point to a mandate because, under the facts assumed, longer hospital stays are medically necessary and should therefore be covered under an insurance policy. Arguably this is true. However, if insurance companies take the initial position that such stays are not medically necessary, the burden is on the patient to file an appeal. Only a subset of patients who are denied coverage will file an appeal,[39] and even if the insurance company loses every such appeal it still may be in its best interest to deny coverage in order to save costs. Therefore, even where a treatment *should* be covered by a policy because it is medically necessary and not otherwise excluded, the law may, in certain circumstances, want to require such coverage in order to prevent widespread denials of coverage for the treatment and the resulting administrative expense and inconvenience to patients.

Therefore, while political unpopularity of coverage decisions is not a sound justification for regulating the substance of health insurance contracts, doing so to effect health policy is a sound justification. The interests of health insurers and those of public health will not always be well-aligned. Mandates can, in certain circumstances, overcome that problem. On this theory, the necessary conditions for a mandate would be (1) evi-

39. While not much is known about the number of individuals who file appeals following a coverage denial, evidence suggests that it is a relatively small number. *See* Kenneth H. Chuang et al., *Independent Medical Review of Health Plan Coverage Denials: Early Trends*, 23 HEALTH AFF. 163, 167 (2004) (finding that a very small percentage of individuals appealed health plan coverage decisions to an independent medical review board); David M. Studdert & Carole R. Gresenz, *Enrollee Appeals of Preservice Coverage Denials at 2 Health Maintenance Organizations*, 289 JAMA 864, 865 (2003) (two plans with several million enrollees each had 13,033 and 2,223 appeals, respectively, in a given calendar year). Neither of these studies actually tells us, of the individuals who are denied coverage, how many appeal. Nevertheless, they support an inference that the appeal rate is likely to be significantly less than 100%.

dence of a significant number of coverage denials for a particular treatment and (2) evidence that health outcomes would be improved by providing health insurance coverage for such treatment.[40]

4. Cognitive Shortcuts and Biases

Another possible justification for mandating benefits is to address decisionmaking shortcuts and cognitive biases that might otherwise result in suboptimal insurance purchases. When deciding to purchase a health insurance policy, an individual must consider a large number of factors: his or her risk of loss, desired scope of coverage (not just which services are covered, but copays, deductibles, physician networks, etc.), risk tolerance, and premium tolerance, all in the context of unknown medical risks. Substantial evidence exists that many individuals have difficulty making decisions that involve a large number of factors.[41] This type of complex purchasing decision is susceptible to both decisionmaking shortcuts and cognitive biases that might result in suboptimal insurance purchase either because purchasers make poor decisions or insurance companies structure their products to take advantage of purchasers' cognitive limitations. This subpart will look first at decisionmaking shortcuts, before examining cognitive biases that may affect insurance purchase.

a. Decisionmaking Shortcuts

While economic models have long assumed a fully rational decisionmaker who acts always to maximize his or her preference satisfaction, many today believe that the model of a boundedly rational decisionmaker is more realistic.[42] The basic

40. In order for this second condition to be met, we would need evidence that the treatment at issue is price elastic. If not, there would be no need to mandate insurance coverage for such treatment, as individuals would receive the health-improving treatment absent insurance coverage. Note that, as with each market problem identified in this section, even if the two conditions are met, there would still need to be a valid justice claim or positive cost-benefit or cost-efficiency analysis to support a mandate.

41. *See* Korobkin, *supra* note 17, at 53–54 ("In a survey of health insurance purchasers for large corporations . . . twelve percent reported that they made purchasing decisions based on only a single variable!"); *see also* Troy A. Paredes, *Blinded by the Light: Information Overload and its Consequences for Securities Regulation*, 81 WASH. U. L.Q. 417, 440–41 (2003).

42. *See* Korobkin, *supra* note 17, at 47–48.

idea is that decisionmakers use various cognitive shortcuts to arrive at decisions, and that the use of such shortcuts is often rational, given the time and other costs involved in making a fully deliberative decision.[43] One of the simplest strategies,[44] so-called lexicographic decisionmaking, involves the purchaser choosing "the option with the highest ranking on the most important attribute."[45] If premiums are the most important factor to a health insurance purchaser, under the lexicographic model he or she would simply select the health insurance plan that offers the lowest premiums, disregarding other factors. A more complex decisionmaking model is a modified weighted adding strategy, where the decisionmaker makes "trade offs among desirable features of health insurance plans," but only includes high-importance factors in his or her weighting.[46]

The implications of these decisionmaking strategies for health insurance purchasing are varied. One primary issue is that, to the extent health plans compete for business, they likely do so only with respect to highly salient features such as price. Given that most purchasers likely use various decisionmaking shortcuts that limit the number of factors they consider, the number of attributes on which health plans compete is likely quite limited.[47] Professor Korobkin has posited that:

> [t]he area in which information comparisons are most likely to be tractable is price; that is, monthly payments, copayments, and deductibles are probably the most readily comparable attributes for most health care consumers. If the hypothesis that price attributes are easier to compare than nonprice attributes is correct, then consumers are likely to adopt noncompensatory choice strategies based on price, to the exclusion of benefits and services.[48]

Insurers, in turn, "are likely to underprovide any benefits that are not among the most important plan attributes" for purchasers.[49]

> Even customers who would be willing to pay the marginal cost of higher-cost services if asked to evaluate individually

43. *See, e.g.*, Paredes, *supra* note 41, at 439–40.
44. *Id.* at 438.
45. *See* Korobkin, *supra* note 17, at 49.
46. *Id.* at 50.
47. *Id.* at 53, 57–58.
48. *Id.* at 56.
49. *Id.* at 58.

> the value of each feature of an [insurer]'s benefit package might not reward that high quality when an [insurer] offers it as part of a large and complex bundle of services.[50]

The end result is that there is reason to believe that it may be rational for insurers to exclude higher-cost services because, as long as they focus on price, they will not risk losing significant numbers of customers. Mandated benefit laws could be used to remedy insurance companies' behavior by ensuring that they cover higher-cost services that consumers would otherwise value and be willing to pay for. Of course, the trouble in adopting this approach is that it is very difficult to determine *ex ante* what consumers value and what they would be willing to pay for.

b. Problems of Risk Assessment and Cognitive Bias

In addition to decisionmaking shortcuts, individuals are also affected by problems of risk assessment, an important part of health insurance purchasing decisions. Psychological studies have shown that individuals are susceptible to a variety of biases in estimating their personal risks. In simplest terms, these biases result in individuals systemically underestimating certain types of risks (those which are deemed controllable by personal action, those with which the individual has little personal experience, or those which are not particularly memorable)[51] and overestimating other types of risks (those that are particularly memorable or spectacular).[52]

Such biases could affect decisions to purchase any health insurance (referred to earlier as a macro-level decision). However, in the context of requiring specific coverage provisions, what we are concerned with is how such biases may affect decisions to purchase or forgo various riders (that is, micro-level decisions). Required coverage provisions may be justified on

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50. *Id.* at 59.

51. *See* JUDITH H. HIBBARD ET AL., DECISION MAKING IN CONSUMER-DIRECTED HEALTH PLANS 5 (2003), *available at* http://assets.aarp.org/rgcenter/health/2003_05_cdp.pdf (describing optimism bias); Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, *in* JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 3, 11 (Kahneman et al. eds., 1982) (discussing availability heuristic).

52. *See* Paul Slovic et al., *Fact Versus Fears: Understanding Perceived Risk*, *in* JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 463, 466–67; Tversky & Kahneman, *supra* note 51, at 11.

the basis of overcoming cognitive bias. In order to do so, the following necessary conditions would need to be present: (1) the cognitive bias must result in systemic under-estimation of the risk of loss associated with the benefit at issue[53] and (2) the first condition results in negative health outcome(s).

These two conditions are not easy to define, let alone satisfy. In order to apply the first condition, some understanding of what constitutes "systemic" under-estimation of risk is needed. Would a simple majority suffice? Or would some form of super-majority be required? Such a decision would turn on the perceived conditions under which market intervention is justified. For example, does it vary with the severity of the negative health outcome? Does it matter if the affected group is small in absolute terms, but a particularly vulnerable minority? The second condition, a resulting negative health outcome, also needs more clarification. Is it enough that one person suffers a negative health outcome because of condition one being met? Or would some form of cost-benefit analysis be necessary to determine whether a negative health outcome has resulted from the lack of a mandate?

For example, let us assume that coverage for mental health care is excluded from the standard health insurance contract and that one or more cognitive biases result in individuals under-estimating their risk of requiring such care. Let us assume that seventy-five percent of the United States population believes their risk of developing mental illness to be "below average." Because only fifty percent of the population can actually be at or below average in terms of their risk, this suggests that the remaining group—in this example, twenty-five percent of the population—is incorrect in its estimation of mental-illness risk. While this group believes itself to have below-average risk, it is in fact at above-average risk for developing the disease. The result may be that these individuals will fail to purchase mental health coverage, despite above-average risk. The question to be answered is whether this underestimation by twenty-five percent of the population is systemic. A quarter of the population is not insignificant, but is it enough to justify interference with the market? Are we more willing to take action if the twenty-five percent represents a particularly vulnerable population? Or perhaps what is considered sys-

53. Systemic over-estimation of risk would also result in inefficient health care purchasing, but not an inefficiency that could be addressed by mandated benefit laws. As a result, it is omitted from this discussion.

temic varies with the severity of the negative health outcome. One could make an argument that the cognitive bias that results in turning down specific insurance coverage is, in and of itself, a bad outcome because it potentially represents an inefficient use of resources.[54] I argue, however, that our concern here is only triggered if negative health outcomes result among individuals in the group of above-average risk who fail to realize their riskiness.

Evaluating health outcomes, however, is an incredibly different task. One possible approach to defining a negative health outcome would be to evaluate whether the health of those affected by the cognitive bias is likely lowered by the absence of a benefit mandate. If the treatment at issue is one that individuals are able to pay for out of pocket, health outcomes may not be negatively affected. Similarly, we would not expect to see health outcomes change if demand for the treatment is not significantly price elastic. However, if it is lack of insurance that results in a lack of treatment, our second requirement is likely satisfied, provided the treatment being mandated is clinically effective.[55] As with establishing evidence of cognitive bias, establishing negative health outcomes is a data-intensive exercise. The end result appears to be that, while cognitive bias is a permissible justification for mandated benefit laws, evidentiary and definitional issues may prevent the cognitive bias justification from being much used in practice.

54. The argument for cognitive bias alone being sufficient to cause an undesired outcome would be made on efficiency grounds. Normally, we think that individuals will make preference-maximizing decisions. However, cognitive bias can lead individuals to make decisions on the basis of flawed information. As a result, individuals affected by cognitive biases might not make preference-maximizing decisions, therefore decreasing welfare.

55. One recent study reminds us of the need to pay attention to utilization rates post-insurance coverage. Utilization of some services may not increase, even if the marginal cost is zero. *See, e.g.*, Barak D. Richman, *Insurance Expansions: Do They Hurt Those They Are Designed To Help?*, 26 HEALTH AFF. 1345 (2007) (finding that certain populations have lower utilization rates of pharmacy and mental health benefits, even at a heavily-subsidized price and controlling for income and education).

5. Overcoming Problems in the Group Market

Employers provide group health care coverage to a majority of working Americans.[56] While there are many benefits to this employer-based system, the employer-based group purchasing model may lead to a form of market failure that could be corrected by mandated benefit laws.

Economic theory predicts that employers should act as agents in deciding which health benefits to offer employees.[57] When employers offer health benefits, the cost of doing so is thought to directly reduce wages.[58] If, however, employers offer health benefits that are not valued by workers, total compensation would need to rise to provide employees with the same level of utility as they would enjoy if compensation was paid entirely in cash.[59] This pressure should result in employers choosing health benefits that reflect the preferences of their employees.[60]

While economic theory would predict that employers will offer health plans that reflect employees' preferences and therefore maximize utility, there is concern that certain details of a health plan may be difficult for the employee to discover or understand.[61] Where employees are not in a position to fully evaluate the utility of the benefit offered, employers may not act in the best interests of their employees and may instead

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56. In 2007, 62.2% of non-elderly Americans had employment-based health insurance coverage. Paul Fronstin, *Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the March 2008 Current Population Survey*, Employee Benefit Research Institute, Issue Brief No. 321, Sept. 2008 at 5, *available at* http://www.ebri.org/publications/ib/index.cfm?fa=ibDisp&content_id=3975. Among all Americans, including those over age sixty five, fifty-four percent have employer-sponsored health insurance, sixteen percent are uninsured, twelve percent have Medicaid or other public coverage, fourteen percent have Medicare, and five percent have private, non-group coverage. Kaiser Family Foundation, Health Insurance Coverage in the U.S., 2006, http://facts.kff.org/chart.aspx?ch=477 (coverage data are for 2006).

57. *See* Michael Chernew et al., *Quality and Employers' Choice of Health Plans*, 23 J. OF HEALTH ECON. 471, 472 (2004).

58. The actual effect, of course, is much more nuanced. For a review of the relevant literature, see Jonathan Gruber, *Health Insurance and the Labor Market*, *in* HANDBOOK OF HEALTH ECONOMICS 645, 690–95 (Anthony J. Culyer & Joseph P. Newhouse, eds., 2000).

59. *See* Chernew et al., *supra* note 57, at 472.

60. *See id.*

61. *See id.* (positing that health plan quality may be partly unobservable to employees).

make decisions that minimize cost.[62] This hypothesis has implications for employer micro-level coverage decisions and mandated benefit laws. Micro-level coverage decisions are likely to be difficult to observe by employees or potential employees. First, when prospective employees are evaluating an offer of employment, the information they receive regarding available health benefits is likely to be limited to macro-level information such as plan provider, cost sharing requirements, and employee premiums.[63] A prospective employee who is particularly interested in the coverage of a certain treatment or service might inquire about that coverage, but many will not. When existing employees are making their annual benefit elections during open enrollment, they also are commonly provided with macro-level benefit information. Again, if there is a specific treatment or service they are concerned about, they might inquire with the human resources department as to whether there are any coverage differences between the plans offered, but this is likely to be the exception.[64]

Given the likelihood of a lack of information regarding micro-level coverage decisions, one might expect employers to exclude benefits that are particularly expensive (much as insurance companies are likely to do). This is a reasonable hypothesis, but there have not been any studies of this issue.[65] There are only a few studies of employer decisionmaking regarding health plan offerings, and those studies tend to focus

62. *Id.* (examining relationship between employer decisions regarding which health plans to offer employees and performance data available for those plans; finding that even though performance data may be partially unobservable by employees, employers did not take advantage of this and did not preferentially offer plans with poor performance scores).

63. ERISA requires employers to provide detailed information regarding their health plans, but only to plan participants and beneficiaries, not to prospective employees. *See* 29 U.S.C. § 1021(a) (2000); 29 C.F.R. § 2520.102-2 to 102-3 (2007).

64. Unless the individual has already developed a particular condition or knows that she is at risk for a particular condition, it would be very unlikely that a specific inquiry as to micro-level coverage terms would be made, due to the sheer number of coverage possibilities involved. For example, if the individual had no reason to believe that she would ever require "durable medical equipment," she would be unlikely to examine the plans offered to determine which plans cover such equipment.

65. We do know, however, that most self-insured employers do cover mandated benefits voluntarily. *See* Jonathan Gruber, *State Mandated Benefits and Employer-Provided Health Insurance*, 55 J. PUB. ECON. 433, 455–58 (1994). What is unclear is whether employers do so because they have come to the same conclusion as legislators with respect to the benefits or whether the effect of the state mandate is to create market pressure on self-insured employers to offer such benefits in order to compete for workers.

either on interviews with benefits managers regarding health plan decisionmaking or analyzing the extent to which employer choices of plans reflect available quality data.[66] Anecdotally, it appears that most large employers engage human resources consultants to help them structure their health plans, while small employers rely primarily on insurance brokers.[67] Unfortunately, little is known about the guidance that human resources consultants provide to employers or the evidence that they present to employers, nor the extent to which employers engage these micro-level coverage decisions.

In addition to employers potentially taking advantage of lack of employee interest in or awareness of micro-level coverage terms, there is also the general problem in the group market of less-than-complete choice. For a majority of individuals with employer coverage, only one health plan is made available to employees.[68] As Professor Korobkin has explained:

> For the market to operate efficiently, employers must select health care plans that their employees would select on their own, at least most of the time. If employers select less-expensive, more limited health plans than employees would choose themselves if they had complete purchasing autonomy but had to pay the full cost of the coverage, the market might currently provide an inefficiently low level of coverage—one that benefits mandates could remedy.[69]

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66. *See, e.g.*, Judith H. Hibbard et al., *Choosing a Health Plan: Do Large Employers Use the Data?*, 16 HEALTH AFF. 172 (1997) (study involving interviews with employer purchasers regarding their use of clinical outcomes data); U.S. GEN. ACCOUNTING OFFICE, HEALTH CARE QUALITY: IMPLICATIONS OF PURCHASERS' EXPERIENCES FOR HCFA, GAO/HEHS-98-69 (1998) (case study of four large purchasers of managed care for employees and how they incorporated quality-related data into their purchasing and monitoring decisions); Anthony T. LoSasso et al., *Beyond Cost: 'Responsible Purchasing' of Managed Care by Employers*, 18 HEALTH AFF. 212 (1999) (two surveys of employers regarding health plan purchasing criteria).

67. *See* Robert S. Galvin & Suzanne Delbanco, *Why Employers Need to Rethink How They Buy Health Care*, 24 HEALTH AFF. 1549, 1551 (2005). Many small employers purchase insurance rather than self-insure, so they do not face the same coverage decisions. *See* KAISER FAMILY FOUNDATION, *supra* note 21, at 148 ex.10.3 (finding that only twelve percent of workers employed by small firms are covered by self-insured health plans).

68. Among employers who offer health insurance, eighty-seven percent offer only one plan. KAISER FAMILY FOUNDATION, *supra* note 21, at 58. However, because large employers are more likely to offer multiple plans, forty-nine percent of covered workers have a choice of more than one health plan. *See id.*

69. Korobkin, *supra* note 17, at 24–25.

In addition, the dynamics of group purchasing in the employment context involve an employer aggregating the preferences of its employees. If the majority of its employees are not at risk of developing diabetes, the employer might select an insurance plan that does not cover diabetes-related supplies. For the minority that is at risk for diabetes, they are out-voted by the majority and cannot get access to such coverage. Mandated benefits could overrule this aspect of preference aggregation.

Therefore, mandated benefit laws could be used to overcome shortcomings in the group market. To be justified in doing so, we would need evidence of either (1) employers providing an inefficient level of coverage to employees or (2) a minority of employees losing access to certain coverage because of preference aggregation. The second possible justification is very similar to the general problem of market failure that leads to non-availability of coverage. And, as we are becoming familiar with at this point, establishing either of these necessary conditions might be quite difficult.

C. When Should a Benefit Mandate be Used to Address These Problems?

Given our limited health care resources, it is not sufficient to simply identify a market failure that a mandated benefit law can effectively address. We cannot afford to cover every possible medical service, so we must have some method of distinguishing which services should be covered by mandates and which should not be covered. This Part argues that a mandate must have either (1) a successful justice claim that necessitates its passage or (2) a positive cost-benefit or cost-effectiveness analysis. Each of these necessary conditions will be analyzed in turn.

1. Justice

As mentioned above, it is not enough that a benefit is not covered by a standard health insurance contract and some form of market failure prevents such coverage from being effectively available. We need something more to distinguish benefits that should be mandated and benefits that we can require individuals to pay for out of pocket. One way to distinguish between such benefits is on justice grounds. Given the prohibitive cost of many health care services, failure to include a

particular benefit in the standard health insurance contract can effectively restrict access to the treatment for many individuals.[70] Because access to medical services can affect the well-being of individuals in fundamental ways, the decision about whether to mandate a benefit that is otherwise excluded from the standard health insurance contract involves important issues of distributive justice.[71]

A top-down approach to using an appeal to justice to support a mandated benefit would be difficult at best. We would need a consensus on a theory of justice that applies to health care. This theory of justice would need to guide decisions regarding (1) what should be covered under all health insurance contracts and (2) given our limited resources, and our unwillingness to devote limitless resources to health care, which services deserve priority over others.[72] Widespread agreement on these two issues would likely be impossible.[73]

A bottom-up approach would be far more practical. For example, a rights-based theorist and an egalitarian could offer completely different theoretical reasons to support a specific mandate.[74] The theories proffered for why the mandate is required by justice could be incompatible, but they might lead to the same result. So while coming to agreement on a governing theory of justice for health care may be unrealistic, there may be certain mandates that many theories of justice support. Where there is substantial agreement on what justice requires in the case of a specific coverage requirement, such agreement can (and should) be used to justify requiring coverage of the treatment or service at issue.

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70. *See* Norman Daniels & James Sabin, *Limits to Health Care: Fair Procedures, Democratic Deliberation, and the Legitimacy Problem for Insurers*, 26 PHIL. & PUB. AFF. 303, 304 (1997).

71. *Id.* at 304–05.

72. *See generally* Norman Daniels, *Health-Care Needs and Distributive Justice*, 10 PHIL. & PUB. AFF. 146 (1981) (discussing the development of a theory of health care needs).

73. For a discussion of Oregon's attempt to tackle these issues, see Jonathan Oberlander et al., *Rationing Medical Care: Rhetoric and Reality in the Oregon Health Plan*, 164 CANADIAN MED. ASS'N J. 1583 (2001).

74. For an example of how a bottom-up approach might lead to ethical consensus, see Andrew Light, *The Case for a Practical Pluralism*, *in* ENVIRONMENTAL ETHICS: AN ANTHOLOGY 229 (Andrew Light & Holmes Ralston III eds., 2002).

2. Cost-Benefit and Cost-Effectiveness Analysis

Another valid method of determining which benefits should be mandated is by performing either a cost-benefit or cost-effectiveness analysis. Under a cost-benefit analysis, the cost of the mandate at issue is compared with the benefits it delivers. While this sounds simple, accurately determining both the cost of a mandate and its benefits is an inexact science. In particular, it can be difficult to determine exactly what the benefits are and how their value should be determined.[75] Nevertheless, in many cases it is possible to come up with well-grounded estimates and establish that the cost of a mandate either is equal to or less than the benefits it provides. In such a case, a mandate would have the additional justification it needs to support passage.

Of course, one might be puzzled as to why a service with a positive cost-benefit analysis would need to be mandated. After all, where there is a benefit that exceeds the cost of the mandate, insurance companies should voluntarily cover the service at issue. Ordinarily this is true, assuming that the insurance company has access to, or conducts its own, sound cost-benefit analysis. However, some benefits are only achieved over time, and a single insurance company, which gains and loses covered individuals constantly, may not have a long enough time horizon to capture long-term benefits.

Cost-effectiveness analysis measures benefits in natural units of outcome for the treatment being evaluated.[76] For example, depending on the treatment, one might use an increase in life years, cases prevented, or cases detected.[77] The result, the cost-effectiveness ratio, shows the additional cost per additional unit of outcome achieved.[78] This is most helpful in comparing the proposed mandate with alternative treatment that is either already covered by standard health insurance policies, or with alternative treatment patients currently pay for out of pocket. For example, in evaluating an infertility treatment mandate, it would allow a comparison between the cost-effectiveness of mandating coverage for in vitro fertilization

75. *See* Jeremiah Hurley, *An Overview of the Normative Economics of the Health Sector*, *in* HANDBOOK OF HEALTH ECONOMICS 55, 96–97 (Anthony J. Culyer & Joseph P. Newhouse eds., 2000).

76. *Id.* at 97.

77. *Id.*

78. *Id.*

with the cost-effectiveness of tubal surgery, which is an alternative treatment for infertility covered by most standard health insurance policies. If the mandate is more cost-effective than currently covered alternative treatment, a mandate would be justified (assuming that covering the comparison treatment is justified in the first place).

3. Justice Versus Economic Analysis

While justice and economic analysis can both be used to justify a mandated health benefit law where market flaws exist, they would likely be appealed to under different circumstances. Where the market flaw concerns non-coverage for an entire disease or condition, a justice claim would need to be made in order to justify bringing treatment for that disease or condition under the health insurance umbrella. Doing so, after all, would involve a very fundamental decision regarding which medical risks should be shared. On the other hand, where the market flaw concerns coverage for a particular type of treatment, and coverage for the underlying disease or treatment is already provided for, an appeal to a positive cost-benefit or cost-efficiency analysis would be more likely. For example, justifying a mandate for infertility treatment would more likely be made on justice grounds because all treatment for the disease of infertility is generally excluded from health insurance contracts. On the other hand, a mandate addressing a particular type of treatment for heart disease would be more likely to rest on economic anlayis, because we have already made the decision that treatment for heart disease generally should be covered by health insurance.

D. The Case for Value-Based Mandates

Under the framework outlined above, the first step in mandating a particular benefit would be to establish that one of the market failures outlined above exists, and that either justice or economic analysis supports the mandate. Our first step, which is being very specific about the problem we seek to address, allows us to tailor the solution to that problem. For example, in the infertility case study below, if one of our justifications for an infertility treatment mandate is to reduce high-order multiple births, our mandate should not simply mandate coverage for "infertility treatment," but should only cover

treatments that adequately control risk of high-order multiples. Just as we are seeing strong movement toward "evidence-based medicine" and "value-based insurance design,"[79] we should embrace value-based mandates as a valuable health reform tool. I have chosen the term "value-based mandate" rather than the narrower "evidence-based" term intentionally. While many mandates may be based on clinical evidence, or even economic value, we might also tailor a mandate based on non-economic values, such as justice or fairness. "Value," then, can take many different forms.[80]

Many, if not most, value-based mandates will likely run up against political opposition. Americans are uncomfortable with interference in the doctor-patient relationship.[81] While value-based mandates would indirectly interfere with the relationship, they would interfere nevertheless. Despite the likely political resistance to value-based mandates, there are strong arguments in their favor. First, there is an acknowledged need for rationing in our health care system. We have limited health care resources and potentially unlimited health care demands. There are huge regional variations in the clinical practice of medicine, suggesting that doctors are not always disciplined in following clinical best practices.[82] One possible value-based tool for encouraging more efficient use of medical resources is to condition reimbursement for medical services on following clinical best practices. Doing so should be a very powerful incentive to change practices to conform to the best available evidence. In addition, when one considers that mandates should generally be enacted to counter market failure, we should be comparing the political feasibility of a value-based mandate against non-coverage, which is the typical status quo (at least with respect to new mandates).

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79. *See generally* Michael E. Chernew et al., *Value-Based Insurance Design*, HEALTH AFF., 2007. Professor Clark Havighurst has been arguing for the inclusion of third-party clinical practice guidelines in health insurance contracts for some time. *See* HAVIGHURST, *supra* note 2, at 222–64.

80. Using value in this manner is broader than how "value" is typically used in the term "value-based insurance design." Value-based insurance design is often based solely on cost-effectiveness. *See, e.g.*, Kathryn Fitch, *Value-based Insurance Design (VBID): Questions Adopters Should Ask*, MILLIMAN HEALTH PERSPECTIVES, Summer 2008, *available at* http://www.milliman.com/expertise/healthcare/publications/perspectives/pdfs/Health-Perspectives-Summer-2008.pdf.

81. *See, e.g.*, MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS AND ECONOMICS OF RATIONING MECHANISMS 64 (1997).

82. *See* Foote & Town, *supra* note 28, at 1637.

There are obvious shortcomings with this approach. First, legislatures appear to be ill-suited to the type of detailed findings and decisionmaking that a move to value-based mandates would entail.[83] The likely solution would be to create some type of expert administrative body to perform the analysis required by this approach and, perhaps, to be charged with the rulemaking itself.[84] This would not be an easy task, and it would be an ever-evolving one. In addition, there would likely need to be some form of appeal process, where an individual can request coverage for a particular service even though it falls outside of the provisions of the finely-tailored mandate.[85] This could be expensive and time consuming, although it may not represent a significant change over the current appeals process that applies to employer-provided health insurance coverage.[86]

The benefits to this approach, however, appear to outweigh the negatives. By crafting value-based mandates, patients would be provided with a valuable resource. Patients are currently overwhelmed with the amount of information available regarding medical treatment options.[87] While some patients actively research their options, many, in the end, simply defer to their doctor's advice.[88] Value-based mandates would provide patients with a very valuable signaling device. Imagine you are a patient with heart disease, and there is a value-based mandate that insurance companies cover bypass surgery for patients with your condition. Part of the rationale for the bypass surgery mandate was that it was cost-efficient as compared to treatment with a stent. As a result, insurance compa-

83. For a detailed look at the limitations of the legislative process in the mandated benefit context, see Hyman, *supra* note 32.

84. The Comparative Effectiveness Research Act of 2008, introduced in the Senate in 2008, would create such a body to conduct research comparing the effectiveness of various medical technologies and treatments. S. 3408, 110th Cong. (2008).

85. For example, if there is a coverage mandate for the most clinically effective treatment of a particular medical condition in order to increase suboptimal utilization of the service, we may want to allow individuals who desire an alternative treatment for the same underlying condition to appeal for coverage of the alternative treatment. While burdensome, such an appeal process would give the system flexibility to respond to individual patients' circumstances.

86. Participants in, and beneficiaries of, employer-sponsored health plans have extensive rights of appeal under ERISA. *See* 29 C.F.R. § 2560.503-1.

87. For a discussion of decision-making in the medical context, see Amy B. Monahan, *The Promise and Peril of Ownership Society Health Care Policy*, 80 TUL. L. REV. 777, 818–22 (2006).

88. HALL, *supra* note 81, at 41.

nies no longer cover stents for individuals with your presentation. Nevertheless, your treating physician recommends a stent (because it is the treatment norm in your geographic area), but you learn that your insurance company will not cover the cost of the stent, only bypass surgery. You may initially be infuriated that the insurance company is undermining your trusted physician's advice. But you will also likely have a conversation with your physician regarding *why* she recommended a stent instead of bypass surgery. Without having the information costs associated with conducting your own medical research, you have been given information regarding your treatment options.[89] It is now up to your doctor to make the case for why the stent is preferable to the bypass surgery, either for an appeal of the coverage decision or to convince you that it is worth a higher out-of-pocket cost. Essentially, value-based mandates change defaults. Of course, for this approach to work the public would need to have significant trust in the administrative body crafting the value-based coverage provisions.

The three case studies below are intended to illustrate a range of issues associated with adopting a value-based approach to mandated health benefit laws. Before moving on to these case studies, a brief discussion of the weaknesses of this proposal is due.

E. Acknowledged Weaknesses

Any time an attempt to fix a market failure is made, as this Article proposes, the outcome will likely not be as efficient as that which could be achieved through a fully functioning market. Mandates limit choice, and limiting choice creates inefficiencies. This does not mean, however, that mandates are without value. It means that mandates are a second-best solution, necessitated by market failure.[90]

Interfering in markets, even with the best of intentions and well-grounded justifications, can result in unintended consequences. Relevant to our discussion, when we mandate that a certain benefit be covered by insurance, we may be making the market for that service less competitive than it was when

89. Which is a good thing, because "[p]atients rarely abandon doctors, reject doctors' recommendations, or demand second opinions." Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643, 652 (internal citation omitted).

90. *See* Korobkin, *supra* note 17, at 66.

individuals were paying out-of-pocket for the service. In health care market segments in which there is patient demand but little to no insurance coverage, market competition tends to decrease prices while improving outcomes. The market for Lasik eye surgery is often cited as an example of this phenomenon. Although not covered by standard health insurance or vision policies, technology in the field has continued to improve while the real price of surgery has fallen by thirty percent over the last decade.[91]

If an insurance mandate has the effect of making a previously competitive market less so, this would negatively effect not those with insurance, but those who remain uninsured (or, perhaps, those that have inferior government-funded coverage). The remaining individuals in the market without insurance coverage might face higher prices for the service than they did prior to the passage of the mandate or fail to benefit from further reductions in price. This concern may not be significant enough to trump an otherwise justifiable mandate, but it should nevertheless be considered during mandate deliberations.

II. THE INFERTILITY CASE STUDY

Now that this Article has made an initial case for value-based mandates, three case studies of existing mandates are undertaken in order to determine (1) if they are justified and (2) if they can be improved by being made value-based. Infertility treatment makes an interesting and relevant case study for several reasons. First, infertility treatment is expensive. Because mandated benefit laws are frequently criticized for increasing health insurance premiums, examining an expensive mandate is instructive. Also, infertility is considered by many to be a "quality of life" benefit. It neither extends nor preserves the patient's life, and therefore it raises interesting issues with respect to which medical risks should be pooled. There is also a good amount of empirical data on how state insurance mandates for infertility treatment have affected utilization and treatment outcomes, allowing an in-depth analysis of the relative costs and benefits of such treatment mandates as well as effects on health outcomes. Because of the complexity of this

91. *See* John C. Goodman, *Perverse Incentives in Health Care*, WALL ST. J., Apr. 5, 2007, at A13.

example, it receives the most detailed discussion of the three case studies.

This Part begins with some brief background on infertility treatment, and then examines the arguments both for and against mandated coverage of such treatment. After concluding that there are compelling arguments in favor of adopting a mandate for infertility treatment, the case for a value-based infertility mandate is discussed in detail.

A. An Infertility Primer

1. Treatment

Infertility has been defined as the inability to become pregnant after twelve or more months of well-timed, unprotected sexual intercourse.[92] Approximately thirteen percent of married, American couples of reproductive age are believed to be infertile.[93] The majority of infertile women do not seek any medical assistance in becoming pregnant.[94] Of those that do seek medical assistance, many pursue little or no treatment.[95] A very small percentage of infertile women undergo the most advanced infertility treatment, in vitro fertilization.[96]

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92. *See* Practice Committee of the American Society for Reproductive Medicine, *Definition of "Infertility,"* 86 FERTILITY & STERILITY S4, S228 (2006) ("Infertility is a disease. The duration of the failure to conceive should be twelve or more months before an investigation is undertaken unless medical history and physical findings dictate earlier evaluation and treatment."); RESOLVE: The Nat'l Infertility Ass'n, What is Infertility?, http://www.resolve.org/site/PageServer?pagename=lrn_wii_home (last visited Sept. 28, 2008) ("Infertility is a disease or condition of the reproductive system often diagnosed after a couple has one year of unprotected, well-timed intercourse or if the woman suffers from multiple miscarriages. Infertility can be male or female related.").

93. *See* Fernanda Ruiz Nuñez, Infertility Treatments, Insurance Mandates and Birth Rates in the United States 1 (June 2006) (unpublished Ph.D. dissertation, University of Chicago) (on file with author).

94. *See* Debora L. Spar, *Where Babies Come From: Supply and Demand in an Infant Marketplace*, HARV. BUS. REV., Feb. 2006, at 133, 135 (reporting that only thirty-six percent of infertile women in the United States seek medical assistance in conceiving); *see also* WASH. STATE DEP'T OF HEALTH, INFERTILITY MANDATED BENEFITS SUNRISE REVIEW 2 (2001) (reporting that approximately forty-three percent of infertile women raise the issue with their OB/GYN and only twenty-one percent of those are examined to determine the cause of their infertility).

95. *See* Spar, *supra* note 94, at 135.

96. *See id.* (reporting that only one percent of women try IVF); *see also* Nuñez, *supra* note 93, at 61 app.C, tbl.2 (reporting that 3.15% of women currently married or cohabitating and aged eighteen to forty-four years who sought medical help to become pregnant utilized IVF in 2002).

For those who seek medical assistance, diagnosis and treatment of infertility usually follows a standard progression. The first step is for both the woman and man to undergo a series of diagnostic tests to determine the cause of the infertility.[97] Infertility can be caused by physical or hormonal problems in either the man or the woman, and can also be age-related.[98] Often, no distinct cause can be identified.[99] If the couple desires medical treatment, such treatment usually progresses from least invasive and least expensive (drug treatment only) to the most invasive and most expensive option, in vitro fertilization (IVF).[100]

The least invasive treatment, and often the first step in treatment for women who do not ovulate or couples with unexplained infertility, is to treat the woman with ovulation-inducing drugs either on their own or in combination with artificial insemination.[101] Ovulation-inducing drugs, as the name suggests, act through various mechanisms to stimulate ovulation in women who do not regularly ovulate on their own.[102] They are also used on ovulatory women to increase the number of eggs that mature in a given cycle, thereby increasing the chances of conception.[103] The mildest form of stimulation is generally achieved through the use of clomiphene citrate or, more recently, an aromatase inhibitor such as letrozole.[104] More aggressive stimulation can be achieved through the use of a class of drugs called gonadatropins. The response to gonadatropins varies tremendously by dose and individual, but anywhere from one to five or more eggs may be stimulated.[105]

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97. *See* Kaylen M. Silverberg, *Evaluation of the Couple with Infertility in a Managed Care Environment*, 43 CLINICAL OBSTETRICS & GYNECOLOGY 844, 845 (2000).

98. *Id.* at 845–52.

99. *See* John F. Randolph, *Unexplained Infertility*, 43 CLINICAL OBSTETRICS & GYNECOLOGY 897, 897 (2000) (noting that the reported prevalence for unexplained infertility has ranged from six to fifty-eight percent).

100. The standard progression may not be followed where a specific diagnosis contradicts certain treatments. For example, a woman who lacks patent fallopian tubes would not be treated with ovulation stimulation and insemination but would likely proceed directly to IVF.

101. *See* Souzan Kafy & Togas Tulandi, *New Advances in Ovulation Induction*, 19 CURRENT OPINION IN OBSTETRICS & GYNECOLOGY 248, 248 (2007).

102. *See* Alaina B. Jose-Miller et al., *Infertility*, 75 AM. FAM. PHYSICIAN 849, 854 (2007).

103. *See* Randolph, *supra* note 99, at 898.

104. *See* Kafy & Tulandi, *supra* note 101, at 248–50.

105. *See, e.g.*, Rosa Tur et al., *Risk Factors for High-Order Multiple Implantation After Ovarian Stimulation with Gonadotrophins: Evidence From a Large Se-*

Often, the drugs are used in combination with artificial insemination, where sperm are inserted directly into the woman's uterus, which is thought to increase the chances of fertilization in some patients.[106] This treatment protocol is commonly used for three to six months, depending on the individual situation and diagnosis.[107]

The cost and success rate of ovulation induction and artificial insemination vary greatly based on the drugs used and the diagnosis of the patient. Monthly cost for such treatment ranges from $200 to $5000.[108] The price of the treatment rises based on the drugs used and the amount of medical monitoring (blood work and ultrasound examinations) that are done during the treatment cycle. For women treated with clomiphene citrate, success rates have been reported to range from 5.6 to 15% per treatment cycle,[109] while the rate of twin births is 5 to 10%.[110] High order multiples (defined as triplets or greater) resulting from the use of clomiphene citrate are rare.[111] Treatment with letrozole appears to offer slightly better pregnancy rates than clomiphene citrate, with reported success rates ranging from 5.9% to 26.3% per cycle.[112] The rate of multiple-

ries of 1878 Consecutive Pregnancies in a Single Centre, 16 HUM. REPROD. 2124, 2127 (2001).

106. *See* RESOLVE: THE NAT'L INFERTILITY ASS'N, INFERTILITY TREATMENT AND MULTIPLE-GESTATION PREGNANCY 3, http:/www.resolve.org/site/DocServer/Multiple-Gestation-Pregnancy.pdf?docID=621 (last visited Sept. 28, 2008). *But see* Per-Olaf Karlström, Torbjörn Bergh, & Örjan Lundkvist, *A Prospective Randomized Trial of Artificial Insemination Versus Intercourse in Cycles Stimulated with Human Menopausal Gonadotropin or Clomiphene Citrate*, 59 FERTILITY & STERILITY 554, 558 (1993) (noting insemination has not been shown to increase success rates where the infertility is unexplained).

107. *See* Bradley J. Van Voorhis & Craig H. Syrop, *Cost-effective Treatment for the Couple with Infertility*, 43 CLINICAL OBSTETRICS & GYNECOLOGY 958, 965 (2000) (citing a study that suggested that three to four cycles of artificial insemination with gonadatropins is a cost-effective approach to treating infertility); *see also* Serena Dovey et al., *Clomiphene Citrate and Intrauterine Insemination: Analysis of More than 4100 Cycles*, FERTILITY & STERILITY (forthcoming 2008) (manuscript at 5, on file with author) (finding that pregnancy rates per cycle of clomiphene citrate and artificial insemination drop beginning in the third month of treatment).

108. Nuñez, *supra* note 93, at 3.

109. *See* Hananel Holzer et al., *A New Era in Ovulation Induction*, 85 FERTILITY & STERILITY 277, 279 (2006) (finding a 5.6% pregnancy rate); Kafy & Tulandi, *supra* note 101, at 248 (reporting a fifteen percent pregnancy rate among anovulatory women treated with clomiphene citrate).

110. RESOLVE, *supra* note 106, at 3–4.

111. *Id. See also* Kafy & Tulandi, *supra* note 101, at 248 (finding a 0.3% rate of triplets in clomiphene citrate cycles).

112. *See* Kafy & Tulandi, *supra* note 101, at 251 tbl.1 (26.3% with 5mg; 5.9% with 2.5 mg of letrozole). *But see* Ülkü Bayar et al., *Letrozole vs. Clomiphene Cit-*

gestation pregnancy resulting from letrozole treatment appears to be lower than that associated with clomiphene citrate.[113] Treatment with gonadatropins offers the highest likelihood of success, but carries with it a greater risk of multiple pregnancy. As previously mentioned, gonadatropins can stimulate many eggs to mature in a given cycle.[114] Unfortunately, there is no way to reduce the risk of multiple gestation after induction of ovulation without reducing the rate of conception.[115] As a result, multiple pregnancies after induction of ovulation with gonadatropins have come to constitute the majority of all multiple pregnancies related to infertility treatment.[116] The risk of multiples is so high that some in the medical profession question the use of ovulation induction with gonadatropins combined with artificial insemination.[117] The success rates, however, are high. Average success rates for treatment with gonadatropins and artificial insemination appear to range from ten to twenty percent per cycle.[118] Among couples who successfully become pregnant through artificial insemination and gonadatropin stimulation, fifteen to twenty percent bear twins, while an additional five percent will become pregnant with triplets or higher order multiples.[119] Cumulative pregnancy rates appear to peak around four to six cycles.[120]

The final common treatment option for infertility is in vitro fertilization (IVF). While the most invasive and the most expensive treatment option, IVF offers the highest success rates.[121] The first step in IVF is to stimulate multiple eggs to

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rate in Patients with Ovulatory Infertility, 85 FERTILITY & STERILITY 1045, 1045 (2006) (finding that letrozole treatment cycles had a nine percent pregnancy rate, while clomiphene citrate cycles had a twelve percent pregnancy rate).

113. *See* Mohamed F. Mitwally et al., *Pregnancy Outcome After the Use of an Aromatase Inhibitor for Ovarian Stimulation*, 192 AM. J. OF OBSTETRICS & GYNECOLOGY 381, 383–84 (2005).

114. *See* Tur et al., *supra* note 105 and accompanying text.

115. *See* Norbert Gleicher et al., *Reducing the Risk of High-Order Multiple Pregnancy After Ovarian Stimulation with Gonadotropins*, 343 NEW ENG. J. MED. 2, 2 (2000).

116. *Id.*

117. *Id.* at 6 ("[W]e question a treatment algorithm that exposes women to a substantial risk of high-order multiple pregnancy when the alternative of in vitro fertilization is readily available and can potentially eliminate this risk.").

118. *See* Hakan E. Duran et al., *Intrauterine Insemination: A Systematic Review on Determinants of Success*, 8 HUM. REPROD. UPDATE 373, 373 (2002).

119. RESOLVE, *supra* note 106, at 3. High order births are usually the result of a cycle that used gonadatropins to stimulate ovulation combined with artificial insemination. *Id.*

120. Duran et al., *supra* note 118, at 381.

121. *See* Van Voorhis & Syrop, *supra* note 107, at 964–65.

mature by providing ovulation-inducing drugs to the woman (the same drugs that are often used in conjunction with artificial insemination). Shortly before the woman ovulates, she undergoes a minor surgical procedure to remove the eggs.[122] The eggs are then placed in a laboratory dish with the man's sperm.[123] The eggs that fertilize are developed in the lab, usually for a period of three to five days, and examined for quality.[124] The highest-quality embryos are then transferred to the woman's uterus.[125] The number of embryos transferred varies based on embryo quality, the woman's age, and the desires of both patient and doctor.[126] The average cost of an IVF cycle is $10,000 to $15,000.[127] The success rate varies by age, from

122. CENTERS FOR DISEASE CONTROL & PREVENTION, 2005 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 17 (2007), *available at* http://www.cdc.gov/ART/ART2005/508PDF/2005ART508Cover_National.pdf [hereinafter 2005 SUCCESS RATES REPORT]; *see also* Society for Assisted Reproductive Technology, ART: Step-by-Step Guide, http://www.sart.org/Guide_ARTStepByStepGuide.html (last visited Sept. 21, 2008).

123. *See* Society for Assisted Reproductive Technology, *supra* note 122. In some cases, an individual sperm is injected directly into the egg to assist fertilization. The procedure is known as intracytoplasmic sperm injection, or ICSI. *See* AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, PATIENT'S FACT SHEET: INTRACYTOPLASMIC SPERM INJECTION (ICSI) 1 (2008), http://www.asrm.org/Patients/FactSheets/ICSI-Fact.pdf.

124. *See* Society for Assisted Reproductive Technology, *supra* note 122.

125. *See id.*

126. *See* Practice Comm. of the Soc'y for Assisted Reproductive Tech. & Practice Comm. of the Am. Soc'y for Reproductive Med., *Guidelines on the Number of Embryos Transferred*, 82 FERTILITY & STERILITY S1, S1 (2004) (reflecting a revised guideline for the number of embryos to be transferred in IVF cycles). The Practice Committee of the Society for Assisted Reproductive Technology and the American Society for Reproductive Medicine recommend that for patients under age thirty-five with a favorable prognosis, "consideration should be given to transferring only a single embryo." *Id.* For all other patients under age thirty-five, no more than two embryos should be transferred. *Id.* The guidelines further provide that no more than two embryos should be transferred for patients between thirty-five and thirty-seven years of age who have a favorable prognosis, and no more than three for all others in that age group. *Id.* For patients between thirty-eight and forty years of age who have a "more favorable prognosis," consideration should be given to transfer to no more than three embryos. *Id.* at S2. For all other patients in this age group, no more than four embryos should be transferred. *Id.* at S1–S2. Finally, for patients over age forty, up to five embryos can be transferred. *Id.* at S2. The latest data from the CDC, taken in 2005, reveals that the average number of embryos transferred to women under age thirty-five is 2.4, for women thirty-five to thirty-seven years old the average is 2.6, for women thirty-eight to forty years old the average is 3.0, and for women forty-one to forty-two years old the average is 3.2. *See* 2005 SUCCESS RATES REPORT, *supra* note 122, at 85.

127. Nuñez, *supra* note 93, at 3. Because the probability of a birth resulting from an IVF cycle is approximately one-third, the total expected cost per birth is

37.3% for women under age thirty-five to 10.6% for women aged forty-one to forty-two, as do the percentages of live births having multiple infants, which range from 35.6% among women under age thirty-five to 14.5% for women aged forty-one to forty-two.[128] IVF comprises only three percent of infertility services used in the United States, but it accounts for a substantial number of total births.[129] While IVF has rates of high order multiple births similar to those seen with artificial insemination cycles where gonadatropins are used, the key difference is that the risk of such pregnancies can be effectively controlled during IVF while it cannot be controlled during artificial insemination cycles.

2. High Order Multiples, Health Risks, and Treatment Decisions

Before discussing how infertility treatment is financed, it is critical to discuss the risks to both mother and child associated with multiple-gestation pregnancies, as well as how treatment decisions contribute to such pregnancies.

In the United States, the rate of multiple pregnancies (twin or greater) increased fivefold from 1980 to 2000, in large measure due to the development of infertility treatment.[130] The risks to both mother and child increase as the number of fetuses in a single pregnancy increases.[131] For the mother, the most common complication is preterm labor, but others include anemia, pregnancy-induced hypertension, preeclampsia, gestational diabetes, and premature rupture of membranes.[132]

$30,000 to $45,000. *Id.*; *see also* Spar, *supra* note 94, at 135 (reporting that the average cost for IVF cycle is $12,400).

128. *See* 2005 SUCCESS RATES REPORT, *supra* note 122, at 85. The success rates quoted are for cycles resulting in live births. Specifically, women under age thirty-five had a success rate of 37.3% per cycle; of those who were successful, 32.9% became pregnant with twins, and 4.4% became pregnant with triplets or more. *Id.* Among women aged thirty-five to thirty-seven, success rates per cycle fall to 29.4%, with 27.3% becoming pregnant with twins and 5.0% becoming pregnant with triplets or higher. *Id.* Among women aged thirty-eight to forty, the success rate is 19.7%, with 21.5% becoming pregnant with twins and 4.4% becoming pregnant with triplets or more. *Id.* Finally, for women aged forty-one to forty-two, the success rate drops to 10.6%, with 13.4% of pregnancies resulting in twins and 2.5% of pregnancies resulting in triplets or more. *Id.*

129. Nuñez, *supra* note 93, at 2.

130. Carson Strong, *Too Many Twins, Triplets, Quadruplets, and So On: A Call for New Priorities*, 31 J. OF L., MED. & ETHICS 272, 272 (2003).

131. *See id.* at 274.

132. *Id.* (internal citations omitted).

For the child, the risks are even more severe. As the number of fetuses in a pregnancy rises, the gestational age at birth decreases.[133] While only two percent of single fetus pregnancies are born prior to thirty-three weeks gestational age, fourteen percent of twins and forty-one percent of triplets are born prior to thirty-three weeks.[134] Perinatal mortality rates go up significantly with multiple pregnancies.[135] The death rate per 1000 births is 8.8 for singleton pregnancies, but is 46.8 for twins and 82.6 for triplets.[136] Children of a multiple-gestation pregnancy have both a higher incidence of congenital malformations and long-term handicaps such as cerebral palsy and mental retardation.[137] Not surprisingly, hospital charges are significantly higher for multiple births than single births. One study found average hospital charges of $9,845 for single pregnancies, $37,947 for twins ($18,974 per baby), and $109,765 for triplets ($36,588 per baby).[138]

Despite the risks associated with multiple pregnancies, doctors and patients often agree on courses of treatment that carry a high risk of multiple gestation. From the patient's perspective, multiple factors influence the demand for treatment with a high risk of multiples. One significant factor is that, among the majority of couples undergoing infertility treatment, a multiple pregnancy is not considered a negative outcome.[139] One study of women undergoing ovulation induction and insemination (the treatment most likely to result in multiple pregnancy) found that over seventy-seven percent of those infertile women surveyed would "like to have more than one child in a single pregnancy."[140] Although these findings suggest that

133. *Id.* at 273.
134. *Id.*
135. *Id.*
136. *Id.*
137. *Id.* at 273–74.
138. *Id.* at 274 (citing Tamara L. Callahan et al., *The Economic Impact of Multiple-Gestation Pregnancies and the Contribution of Assisted-Reproduction Techniques to Their Incidence*, 331 N. ENG. J. MED. 244 (1994)).
139. *Id.* at 274–75 (internal citations omitted); *see also* Ginny L. Ryan et al., *A Mandatory Single Blastocyst Transfer Policy with Educational Campaign in a United States IVF Program Reduces Multiple Gestation Rates Without Sacrificing Pregnancy Rates*, 88 FERTILITY & STERILITY 354, 355 (2007) (a pre-treatment survey at one clinic found that twins were the most-desired outcome for twenty-nine percent of couples).
140. Sandva R. Leiblum et al., *Attitudes Toward Multiple Births and Pregnancy Concerns in Infertile and Non-Infertile Women*, 11 J. OF PSYCHOSOMATIC OBSTETRICS & GYNECOLOGY 197, 200, 203 tbl.3 (1990). The same study found that a strong majority of infertile women would prefer having triplets, quadru-

infertility patients may not fully understand the risks associated with multiple gestation, the findings are perhaps not surprising, given the great desire of these couples to have children.[141]

The high cost of infertility treatment is also thought to contribute to the incidence of multiple-gestation pregnancies. For couples paying for infertility treatment themselves (which, as discussed below, describes the majority of infertility patients), there is pressure on the treating physician to maximize success rates while minimizing costs. For couples undergoing ovulation induction and insemination, this means increasing the number of eggs stimulated (and therefore the risk of multiples). For IVF patients, this means increasing the number of embryos transferred. After all, if the patients have enough money for only one round of treatment, there will be great pressure to produce results, even if the risk of multiples is high. These decisions are further complicated by the fact that insemination patients do not discover the presence of a large number of maturing eggs until they have already invested a substantial sum on drugs and medical monitoring.[142] While the treating physician may recommend cancelling the cycle, a couple with limited financial resources and perhaps a desire for multiples, may insist on continuing treatment.[143] With IVF, there is significantly more control over the risks of multiple pregnancy, as doctors and patients can jointly determine how many embryos to transfer. However, given the expense of IVF, many patients (and doctors) are willing to transfer two or more embryos in order to maximize success rates.[144]

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plets, or quintuplets to having no biological children at all. *Id.* at 203–04. For example, 78.7% of women undergoing IVF reported that having quintuplets would be preferable to having no biological children. *Id.* at 203 tbl.3.

141. *See* Ryan et al., *supra* note 139 (discussing in more detail the difficulties of convincing patients that a single pregnancy is the best outcome).

142. Strong, *supra* note 130, at 275.

143. Furthermore, as Strong points out, most doctors will favor patient autonomy and agree to continue treatment. *Id.*

144. *Id.* Given that embryos that are not transferred can be frozen and used to attempt pregnancy in later cycles, one would expect the pressure to transfer many embryos in a fresh cycle would be relatively low. However, there are fees associated with the freezing and storage of embryos, as well as costs associated with a frozen embryo transfer cycle that can amount to thousands of dollars. For example, one large Minneapolis clinic charges $825 to freeze embryos, a storage fee of $275 every six months, and approximately $4600 for the frozen embryo transfer itself. *See* Center for Reproductive Medicine & Advanced Reproductive Technologies, Financial Information, http://www.ivfminnesota.com/Financial_Information.html (last visited Sept. 29, 2008).

Finally, it should be noted that a technique, known as selective reduction, can be used to reduce the number of fetuses in a high order multiple pregnancy.[145] The procedure involves selectively aborting one or more of the fetuses. The primary risk associated with the procedure is a complete loss of the pregnancy.[146] This risk increases with the number of fetuses initially present.[147] For pregnancies that begin with triplets, the loss rate is approximately eight percent, while sextuplet or greater pregnancies have a loss rate of approximately twenty-one percent.[148]

Approximately one-third of infertility patients would not consider selective reduction for religious or ethical reasons.[149] Even for those without religious or ethical objections, it is a "highly stressful and emotionally painful experience for the women who undergo it."[150] These objections and pain, combined with the risk of loss, make selective reduction an undesirable solution to high order multiple pregnancy.

3. Financing

The prevalence of insurance coverage for infertility treatment varies greatly based on the source of the insurance. Currently eleven states have some type of health insurance mandate related to infertility. These laws range from essentially providing full coverage for all infertility services, including IVF, to coverage only for the diagnosis of infertility.[151] Even for those fortunate enough to live in states with comprehensive infertility mandates, they still may lack coverage if their health insurance is provided by an employer that self-insures its health plan. Through the operation of the federal Employee Retirement Income Security Act of 1974 (ERISA), employers with self-insured health plans are exempt from state insurance mandates.[152] The majority of employers do not provide any coverage for infertility services and those that do often do not

145. Strong, *supra* note 130, at 275.
146. *Id.*
147. *See id.*
148. *Id.*
149. *Id.*
150. *Id.* (internal citations omitted).
151. For a discussion of these state laws, see *infra* Part III.D.1.
152. 29 U.S.C. § 1144 (2000). For a more detailed discussion of ERISA preemption in this context, see Monahan, *supra* note 1, at 1371–74.

provide comprehensive coverage.[153] A recent survey reported that twenty-two percent of large employers (those with 200 or more employees) nationwide cover in vitro fertilization, and approximately thirty-nine percent of employers cover drug therapy for infertility treatment.[154] Over sixty percent of all large employers cover medical services related to the diagnosis of infertility.[155] Coverage for all forms of infertility treatment increases with employer size.[156] In addition, average salary at firms offering infertility coverage is higher than the average salary at firms that do not provide such coverage.[157] Among large employers that do not offer any coverage for infertility services, sixty-four percent report that they do not cover infertility because they believe it will lead to increased costs, twenty-nine percent believe that infertility treatment is not the employer's responsibility, and twenty-nine percent believe that infertility evaluation and treatment fall beyond the scope of "basic coverage."[158]

In an attempt to fill the financing gap created by the general lack of insurance of infertility treatment, many infertility treatment providers now offer "shared risk" programs for patients undergoing IVF. For eligible patients, shared-risk programs typically charge a fixed price for a specified number of attempts at IVF.[159] In general, the price charged for a shared-risk program is considerably higher than that charged for a single IVF cycle.[160] If a shared-risk patient is successful in her

153. *See* Nuñez, *supra* note 93, at 9–10, 64 tbl.5 (only one-fourth of all employers purchase health plan coverage for basic infertility treatment and even fewer provide coverage for artificial insemination or IVF).

154. MERCER HEALTH & BENEFITS, EMPLOYER EXPERIENCE WITH, AND ATTITUDES TOWARD, COVERAGE OF INFERTILITY TREATMENT 3 (2006).

155. *Id.* ("Evaluation is covered by 63 percent of large employers.").

156. *Id.*

157. *Id.* at 5. This raises access issues if those who are most likely to have insurance coverage for infertility are also the most likely to be able to afford treatment on an out-of-pocket basis. *See also* Tarun Jain & Mark D. Hornstein, *Disparities in Access to Infertility Services in a State with Mandated Insurance Coverage*, 84 FERTILITY & STERILITY 221 (2005) (further discussing the access issues raised by infertility coverage and infertility mandates).

158. MERCER HEALTH & BENEFITS, *supra* note 154, at 3–4.

159. *See* John A. Robertson & Theodore J. Schneyer, *Professional Self-Regulation and Shared-Risk Programs for In Vitro Fertilization*, 25 J. OF L., MED. & ETHICS 283, 283 (1997).

160. For example, the nation's largest infertility treatment network, IntegraMed, charges slightly more than the cost of two IVF cycles to participate. *See* IntegraMed, Shared Risk Refund Program for IVF Treatment, http://www.integramed.com/inmdweb/content/cons/shared.jsp (last visited Sept. 29, 2008) (explaining

first round of IVF, she ends up paying considerably more for the treatment than she would have if she had not enrolled in the shared-risk program.[161] If a shared-risk patient completes all of the cycles covered by the program (typically three completed IVF cycles) and is not successful, a large percentage of the fee is refunded.[162] A shared-risk patient does not have to commit to undergoing all of the provided rounds or treatment; she may disenroll in the program at any time and receive a significant refund.[163] As Robertson and Schneyer have observed, "[t]he plan's key financial advantage for patients emerges not when treatment succeeds, but when it *fails*."[164]

While advocates of shared-risk plans argue that such plans increase access to IVF, there are important limitations on such access. First and foremost, in order to enroll in a shared-risk program, a patient must meet eligibility criteria determined by the provider.[165] Often the programs have transparent age limitations, but most also have medical parameters that are not specifically disclosed in the enrollment materials.[166] While patients who are eligible and risk-averse may find such plans attractive, it is not clear whether such plans effectively increase access to IVF treatment. Nevertheless, some see value in shared-risk programs as a signal to patients (prior to treatment) about their likelihood for success.[167] For example, if a patient applies for and is accepted into a fertility center's shared-risk program, she may view this as an indication that

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that if an IVF cycle costs $8,000 at a participating center, the shared-risk program fee would be about $18,000).

161. If treatment is successful, no refund is payable and the patient therefore pays more than she would have if she had simply paid out-of-pocket for a single IVF cycle. *See* Robertson & Schneyer, *supra* note 159, at 284.

162. *See* IntegraMed, *supra* note 160 (in the IntegraMed program, the refund is equal to seventy percent of the shared risk fee).

163. *See id.* (explaining that the seventy percent refund is available even if the participant voluntarily drops out of the program). Additionally, IntegraMed reserves the right to terminate an individual's participation in the shared risk program at any time and pay the specified refund rather than providing treatment. *Id.*

164. Robertson & Schneyer, *supra* note 159, at 284.

165. *See id.* at 284; *see also* IntegraMed, *supra* note 160 ("Once IVF is recommended by one of our participating physicians, IntegraMed's clinical staff will review [the patient's clinical information] to determine if a patient is an appropriate candidate for our Shared Risk Refund Program.").

166. *See* Robertson & Schneyer, *supra* note 159, at 284; IntegraMed, *supra* note 160.

167. *See* Robertson & Schneyer, *supra* note 159, at 288 ("When patients qualify, they learn the important fact that the provider considers them a good risk *before* they choose between the shared-risk plan and traditional [fee-for-service].").

the clinic believes her to be a "good risk." She may therefore choose not to enroll in the shared-risk program and instead pay for treatment on a per-cycle basis. Similarly, those who are denied enrollment in a shared-risk program might use such information to reconsider whether IVF provides sufficient potential benefits to be worth the cost.

Infertility patients who neither live in a state with a comprehensive mandate nor work for an employer that voluntarily offers coverage as part of its group health plan must pay for treatments out of pocket, either through a shared-risk plan or on a per-cycle basis. Individual insurance that covers infertility treatment is not generally available, likely due to the presence of adverse selection in the market.[168] Low coverage rates by employers, combined with a lack of available individual insurance coverage for most individuals and the expense of the treatments at issue, suggest that infertility treatment might be a good candidate for mandatory inclusion in health insurance policies. The Subpart below will explore whether an infertility mandate is justified before moving on in the next Subpart to discuss how best to tailor such a mandate in order to make it value-based.

B. Why Mandate Infertility Coverage?

To determine whether an infertility mandate is justified, the first step is to assess whether there is a market problem of the type identified in Part I of this Article that provides an initial justification for a mandate. With respect to infertility, there is both non-availability of insurance coverage due to adverse selection, as well as suboptimal utilization of desired medical treatment. After discussing both of these problems, this Subpart will examine whether there is either a valid justice claim or a positive cost-benefit or cost-efficiency analysis to support an infertility mandate before moving on to discuss how an infertility mandate might be crafted in order to be value-based.

Before beginning, note that three of the permissible justifications from Part I (cognitive bias, overruling adverse coverage determinations, and addressing problems in the group market)

168. *See* M. Kate Bundorf et al., *Mandated Health Insurance Benefits and the Utilization and Outcomes of Infertility Treatments* 3–4 (Nat'l Bureau of Econ. Research, Working Paper No. 12820, 2007), *available at* http://www.nber.org/papers/w12820.pdf.

are excluded from this discussion. There does not appear to be any evidence of cognitive bias resulting in the systemic underestimation of risk associated with infertility treatment. Similarly, because infertility treatment typically is specifically excluded from health insurance (rather than being excluded because of a lack of medical necessity or experimental status), there is no genuine dispute about whether infertility treatment falls within the scope of the health insurance contract. Finally, while there may be problems related to preference aggregation in the group market, there is insufficient data at this point to make an argument on such grounds.

1. Market Failure Leading to Unavailability of Coverage

One problem that can be addressed with mandated benefit laws occurs where adverse selection functions to make insurance coverage for a particular treatment or service unavailable. This Article previously specified two necessary conditions for justifying a mandated benefits law on this basis: (1) the covered individual knows or has reason to know he or she will utilize the benefit at issue, and (2) knowledge of the increased likelihood of utilization is not easily or cost-effectively discovered by the insurance company. Here, the two necessary conditions appear to be easily met. With respect to the likelihood of utilizing infertility benefits, a patient would know things both about his or her fertility and his or her desire for children that are unobservable to the insurance company.[169] Insurance companies would be unable to discover this private information if infertility treatment had not previously been sought. Because of this information asymmetry and the cost of infertility treatment, insurance companies are likely to omit infertility coverage from their standard contract.[170] While a policy rider that covers infertility treatment may be offered, requesting such a rider signals to the insurance company that the insured is likely to utilize such a benefit. The rider is then priced accord-

169. *See id.* at 4 (noting that consumers "are likely to have private information about both their fertility and their desire for children that is highly predictive of their utilization" but is unobservable to insurers).

170. *See id.* ("The fact that infertility is rarely covered by insurance is consistent with, although not direct evidence of, the existence of adverse selection in this market.").

ingly (likely near the expected cost of treatment), and essentially fails to function as insurance.

A mandate to include coverage for infertility treatment in all privately-financed health insurance contracts would effectively address the adverse selection problem just described. Because infertility treatment would be covered by all contracts, the insurance company can spread the risk of loss among the entire insured population, not just those who are affected by infertility. Insured infertile individuals would no longer have to bear the risk of loss themselves; rather, they would receive true insurance coverage against such loss. An infertility mandate would therefore successfully solve the adverse selection problem, but we must determine whether there is a valid justice claim or positive cost-benefit or cost-efficiency analysis before arguing that such a mandate is justified. Before engaging in these analyses, an additional problem that can provide initial justification for an infertility mandate is examined.

2. Increase Suboptimal Utilization

a. The Positive Argument

As discussed in Part I.B.2, mandated benefit laws can be justified where there is (1) evidence of suboptimal utilization of the medical treatment at issue and (2) evidence of price elasticity in patient demand for such treatment. It appears that infertility treatment satisfies both necessary conditions.

While perhaps not without controversy, an argument can be made that there is suboptimal utilization of infertility treatment resulting from negative externalities. In the absence of insurance coverage, infertility patients must pay for such treatments out-of-pocket. In many cases, the cost of such treatments puts a significant strain on the patient's finances.[171] The result is that, for both patient and doctor, there can be significant pressure to make the treatment work quickly. This financial pressure is thought to encourage doctor and patient to make "risky" treatment decisions. For example, a couple pursuing treatment with artificial insemination and ovulation induction might (1) elect a higher dose of stimulation, resulting in additional mature eggs and a greater risk of high

171. *See* Liza Mundy, *A Special Kind of Poverty*, WASH. POST MAG., Apr. 20, 2003, at W8.

order multiples, or (2) decline to cancel an artificial insemination cycle in which a large number of eggs are stimulated, again leading to a greater risk of high order multiples. A couple that is paying for IVF out-of-pocket may make similar choices and pursue an aggressive stimulation regimen and also transfer more embryos than is deemed advisable.[172] Essentially, there is a negative externality in these decisions that the patients are not including in their decision-making process—that is, the cost associated with high-order multiples. The cause of this externality is at least two-fold: (1) many patients who have struggled with infertility affirmatively desire multiples[173] and (2) a standard health insurance contract covers the medical costs associated with high-order multiple births.[174] An infertility mandate may effectively address this externality (although perhaps not in a traditional manner) and lead to better treatment decisions.

Typically, when economists talk of addressing a negative externality, they talk of making the decisionmaker take into account a cost that was not previously factored into the decision. With respect to infertility treatment decisions, that would mean requiring the patients to take into account the costs associated with high-order multiples. Such a solution is theoretically possible. A health insurance contract could be written to exclude medical costs associated with high-order multiple births resulting from infertility treatments. This would almost certainly address the externality, but in a way that is unpalatable because it would either (1) encourage selective reduction of a high order multiple pregnancy or (2) punish the children resulting from such treatment.

However, a mandate for infertility coverage may accomplish the same thing in a more palatable, albeit less direct,

172. Evidence suggests that insurance coverage for IVF does reduce the number of embryos transferred per cycle. *See* Tarun Jain et al., *Insurance Coverage and Outcomes of In Vitro Fertilization*, 347 NEW ENG. J. MED. 661, 663–64 (2002); Meredith A. Reynolds et al., *Does Insurance Coverage Decrease the Risk for Multiple Births Associated with Assisted Reproductive Technology?*, 80 FERTILITY & STERILITY 16, 22 (2003).

173. *See* Leiblum et al., *supra* note 140, at 200.

174. Standard health insurance contracts cover maternity expenses, irrespective of how the child was conceived. As a result, the parents do not need to include the increased costs associated with medical care for multiple gestation pregnancies in evaluating their treatment decisions. *See* Bundorf et al., *supra* note 168, at 11. It is interesting, however, that insurance companies have not been more aggressive in trying to eliminate multiple births, because it is the insurance company that bears the medical costs associated with such births.

manner. Insurance coverage lessens the pressure to make aggressive treatment decisions by lowering the costs of treatment. With significantly reduced out-of-pocket costs, a couple pursuing treatment should be more willing to undergo "gentle" stimulation in an artificial insemination cycle, and more willing to cancel such a cycle if multiple eggs develop. Similarly, a couple undergoing IVF should be more willing to transfer fewer embryos per cycle. Relieving the financial pressure associated with infertility treatment will not completely eliminate high order multiple births, but there is reason to believe it would significantly reduce such births.[175]

Data from states with comprehensive infertility mandates appear to support this hypothesis. Comprehensive infertility mandates have been found to result in a significant reduction in the number of embryos transferred for IVF patients of all ages.[176] A study of the effect of state-level infertility mandates on multiple births found that such mandates increase the number of twin births but significantly decrease the number of triplet or higher births.[177] While a singleton birth is the best outcome from infertility treatment, twin births are significantly less dangerous to both mother and babies than high order multiples and correspondingly less expensive.[178] These data seem to provide at least partial support for the position that infertility mandates can help to address negative externalities in infertility treatment decisions.

Returning to our necessary conditions, there appears to be good evidence of suboptimal utilization of infertility treatment. It is not the case that too little of the treatment is consumed. Rather, it is that the utilization is not of the optimal type (pregnancy maximizing versus high order multiple limiting). Nevertheless, this qualifies as suboptimal utilization. Second, there is evidence both that the demand is price-elastic and that such price elasticity is sufficient to move utilization closer to

175. There would still be non-financial pressures for quick success related to the emotional and physical toll of infertility treatment, and infertility patients may still hold an affirmative desire for multiples.

176. *See* Barton H. Hamilton & Brian McManus, Infertility Treatment Markets: The Effects of Competition and Policy 24 (Oct. 2005) (unpublished manuscript, *available at* http://www.olin.wustl.edu/faculty/mcmanus/IVF10-05.pdf).

177. Nuñez, *supra* note 93, at 29 (triplet births decreased by 60% and triplet and higher order births decreased by 180%). This finding is consistent with the theory that insurance coverage encourages patients to utilize safer, more expensive treatments. *Id.*

178. *See* Strong, *supra* note 130, at 273–74.

optimal levels. That is, there is evidence that reducing the cost of infertility treatments shifts treatment decisions from pregnancy maximizing to high order multiple limiting treatment decisions. It therefore appears that an infertility mandate can be justified on the basis of encouraging optimal utilization of the treatment. This conclusion must remain tentative, however, until the moral hazard issue is discussed immediately below.

b. The Moral Hazard Issue

Having insurance coverage against loss (in this case, against the cost of infertility treatment) can create a so-called moral hazard, where the insured individual becomes more likely to incur a loss than he or she would be in the absence of insurance.[179] The basic idea is that if you do not bear the cost of the loss, you are less likely to seek to prevent it. In the infertility context, the concern is that mandated coverage will lead to individuals electing to receive infertility treatment who would not have done so if they had to bear the treatment cost themselves. Such a position is based on the presumption that demand for infertility treatment is, at least to a certain extent, price elastic. As insurance coverage causes the cost of treatment to decrease, demand may increase among individuals for whom the benefits of treatment are relatively low, resulting in an inefficient level of consumption.[180] One study examining the effect of state-level infertility mandates found evidence of significant moral hazard resulting from such mandates.[181] The authors theorized that benefit mandates would cause low-fertility patients to increase their use of the most advanced infertility treatments.[182] For example, an infertility mandate might result in a couple with a very low probability of success undergoing multiple rounds of IVF where, if they had to pay for such treatments out of pocket, they would not choose to do so.

179. RICE, *supra* note 29.

180. *See* Bundorf et al., *supra* note 168, at 4, 31.

181. *Id.* at 4. Infertility treatment is most effective for couples in the middle of the fertility distribution because it has the largest incremental effect on the probability of a birth for these couples. *See id.* at 7. Mandates are thought to increase utilization among high and low fertility patients. *See id.* at 4–5. For relatively high fertility patients, pursuing treatment has little or no impact on birth rates, but rather increases rates of multiple births. *Id.* at 5. For low fertility patients, insurance may cause them to pursue expensive treatment that has only a small likelihood of success. *See id.* at 5, 34.

182. *See id.* at 10.

The study also theorized that insurance mandates would raise the utilization rates among relatively high fertility patients, who increase their use of low technology treatment.[183] For example, a couple that might become pregnant on their own within two years might elect to undergo low technology treatment, such as drug therapy or insemination, because it is paid for by insurance. If they were paying with their own money, the couple might wait months or years before beginning such treatment. While the study found evidence of moral hazard in the form of increased utilization among both low and high fertility patients, the study design did not permit the authors to test their specific theories regarding relatively low- and high-fertility patients.[184]

This study certainly indicates that moral hazard is a concern with respect to an infertility mandate. However, it must be remembered that, while demand for treatment may be price elastic, it is only so among the infertile population. Covering infertility treatment will not cause those who can conceive children without intervention to seek treatment. In addition, moral hazard is a concern that can be addressed by crafting a mandate to target those for whom treatment provides the greatest expected benefit.[185] Being able to target moral hazard is yet another advantage of using a value-based mandated benefit law.

3. Justice

A valid appeal to justice could support using a mandate to address an existing health insurance market failure. In this sense, justice essentially functions as a rationing mechanism. As a society, we will not be able to afford covering all medical treatments and services in a health insurance contract; justice claims help determine which of these services must be included and which can have lower priority.

This Part takes a very abridged look at the justice claims associated with coverage for infertility treatment by examining the claims of the competing stakeholders. There are several stakeholders in the infertility mandate debate. Included are members of the insured and uninsured populations unaffected by infertility, the infertile population, and the children result-

183. *See id.*
184. *See id.* at 34.
185. *Id.* at 30.

ing from infertility treatments. These groups have competing justice claims, and each will be examined in turn.

Part I concluded that a bottom-up approach to agreement on the requirements of justice is the most feasible. Unfortunately, it is beyond the scope of this Article to lay out how the major ethical theories would inform the debate concerning an infertility mandate. I therefore leave the issue to another article, and to those who are experts in ethical theory. It is enough, for our current purposes, to examine the interests of the stakeholders to begin to get a sense of the competing justice claims that can be made with respect to an infertility mandate.

a. Individuals Unaffected by Infertility

For the insured population unaffected by infertility, an infertility mandate will increase costs and, at the margins at least, may cause some individuals to lose insurance coverage. Estimates vary, but most studies or projections find that the inclusion of infertility benefits in a health insurance policy raises premiums within the range of $7.20 to $27.00 per member per year.[186] We know that employees most frequently cite a lack of affordability for their reason for declining health insurance coverage.[187] Given this relationship between price and coverage, it is possible that the addition of infertility benefits will increase the number of uninsured individuals. However, this argument is perhaps misleading. While the price of insurance and the take-up rate of insurance are inversely related, suggesting that the demand for insurance is price elastic, studies reveal that the price elasticity is very slight.[188] In other

186. *See* WASH. STATE DEP'T OF HEALTH, *supra* note 94, at 4; *see also* Nuñez, *supra* note 93, at 8–9 (summarizing various cost studies, one of which found that a Massachusetts HMO saw premiums increase by $2.49 per member per year, while a study prepared for the National Center for Policy Analysis estimated an increased cost of $105 to $175 per year). In the group market, the premium increase would apply uniformly to all insured individuals. In the individual market, however, state laws vary regarding the extent to which insurance companies may engage in medical underwriting. In some states, it may be the case that individuals who clearly will not utilize infertility treatments may not bear an increased premium from an infertility mandate.

187. *See* David A. Hyman & Mark Hall, *Two Cheers for Employment-Based Health Insurance*, 2 YALE J. HEALTH POL'Y L. & ETHICS 23, 26 (2001).

188. *See, e.g.*, Anne Beeson Royalty & John Hagens, *The Effect of Premiums on the Decision to Participate in Health Insurance and Other Fringe Benefits Offered by the Employer: Evidence from a Real World Experiment*, 24 J. HEALTH ECON. 95, 109–110 (2005) (finding take up rates did not decrease from the baseline rate when premiums of 125% of baseline were charged; take up rates only increased

words, while price does affect health insurance take-up rates, it takes large changes in price to affect enrollment.[189] However, we do need to be sensitive to the fact that while the cost associated with individual mandates may be small, the collective effect may be substantial, and substantial increases in premiums can lead to both increases in the number of uninsured individuals and to negative health outcomes.[190] Nevertheless, because we are at this point examining an infertility mandate on its own merits, the increased cost argument does not appear to be decisive.

Those members of the insured population who do not anticipate utilizing infertility treatment may also oppose an infertility mandate on the grounds that it is contrary to their religious beliefs or personal beliefs about reproduction. The difficulty with this claim is that the risk of loss associated with many treatments or conditions may be morally repugnant to certain individuals.[191] For example, I may object to having

1% when premium was reduced to 75% of baseline); *see also* Michael Chernew et al., *The Demand for Health Insurance Coverage by Low-Income Workers: Can Reduced Premiums Achieve Full Coverage?*, 32 HEALTH SERVICES RES. 453, 464 (1997) (finding that a premium reduction of fifty percent would only increase takeup in the group studied by three percent); Philip F. Cooper & Jessica Vistnes, *Workers' Decisions to Take-Up Offered Health Insurance Coverage: Assessing the Importance of Out-of-Pocket Premium Costs*, 41 MED. CARE III-35, III-41 (2003) (noting that reducing employee contributions for health insurance to zero would only increase take-up rates by six percent); Irena Dushi & Marjorie Honig, *Price and Spouse's Coverage in Employee Demand for Health Insurance*, 93 AM. ECON. REV. 252, 254 (2003) ("A change from paying nothing to paying part or all of the costs results in a 5.2[%] decline in take-up among women and a 1.8[%] decline among men."); Daniel Polsky et al., *Employer Health Insurance Offerings and Employee Enrollment Decisions*, 40 HEALTH SERVICES RES. 1259, 1275 (2005).

189. *See supra* note 179 and accompanying text.

190. *See* Christopher J. Conover, *Health Care Regulation: A $169 Billion Hidden Tax*, 527 POL'Y ANALYSIS 1, 23 (2004), *available at* http://www.cato.org/pubs/pas/pa527.pdf (explaining that as the cost of regulation decreases societal income, individuals have less money to spend on safer products such as cars and homes that may improve their health; one estimate "shows one statistical death for every $7.6 million reduction in societal income").

191. For example, many health insurance contracts cover elective abortions, and all cover the general medical expenses associated with unpopular lifestyle choices such as smoking. *See, e.g.*, HAVIGHURST, *supra* note 2, at 125–32, 140–43 (survey of health insurance contracts found that most contracts cover medically necessary services subject to only a few specific coverage exclusions, only one of which, an exclusion for the treatment of morbid obesity, might be characterized as targeted at an unpopular lifestyle choice); Adam Sonfield et al., *U.S. Insurance Coverage of Contraceptives and the Impact of Contraceptive Coverage Mandates, 2002*, 36 PERSP. ON SEXUAL & REPROD. HEALTH 72, 76 (2004) (finding that 86.9% of health plans surveyed covered surgical abortion, but noting that some of the insurance companies in the study thought abortion meant abortions when pregnancy threatens a woman's health, not simply elective abortions).

some of my health insurance premiums be used to cover other insured individuals' health care expenses related to smoking or the treatment of sexually transmitted disease. Nevertheless, because such treatments are routinely covered by standard contracts of health insurance, I must, if I want insurance coverage, subsidize the cost of such care. Being able to exclude infertility treatments because of the historical accident that such treatments are excluded from the standard health insurance contract appears to be problematic. If we were to start excluding coverage for treatments or services that were unpopular, we would significantly change the nature of health insurance.

Of course, some have moral objections to infertility *treatment* itself. Unlike an objection to treatment of a disease that results from objectionable behavior, such as smoking, this is an objection to the medical treatment itself. Perhaps this is a stronger rationale for allowing these individuals to avoid sharing the costs of such treatment. However, in the general insurance context we do not let individuals opt out of standard coverage terms because they find sharing the risk of such losses objectionable.

b. Infertile Individuals

Infertile individuals, on the other hand, have a justice claim in favor of mandated coverage. These individuals are not able to purchase insurance coverage due to adverse selection, yet they must contribute toward and share the financial risks associated with other medical conditions that do not affect them, such as maternity and child birth expenses. Mandating coverage for infertility treatment would make such insurance available to those who suffer from infertility, and it would pool the risk associated with infertility among the entire insured population, as we do with most other medical services. For those who could not otherwise afford treatment, an infertility mandate would result in access to such health care. By itself, this claim does not appear terribly compelling. Because the treatment is not life preserving or life extending for *infertile individuals*, it must receive relatively low priority compared to other health care needs. The simple inability to pool the risk of loss associated with such care does not seem sufficient to demand a mandate. However, most would acknowledge that bearing and raising children contributes significantly to the parents' well-being. As Norman Daniels points out, being able

to biologically reproduce is clearly part of "normal species functioning."[192]

c. Children Resulting from Infertility Treatment

The children who result from infertility treatment potentially have a compelling justice claim in favor of a mandate. These children benefit from an infertility mandate because it increases the likelihood that, if they are born, they will be born in a singleton or twin pregnancy, rather than a high-order multiple pregnancy.[193] The health outcomes for children born under a mandate should be significantly improved as a result.[194]

Philosophically, it can be problematic to claim that children born of high-order multiple pregnancies resulting from infertility treatment have been harmed by the treatment. This problem is referred to in the philosophical literature as the problem of non-identity.[195] This Article does not attempt to solve the problem of non-identity, as it is an issue that continues to perplex philosophers.[196]

Philosophical problems aside, most people would agree that future children can be harmed by risky treatment decisions, and that policy makers should consider the welfare of these children. Given this argument, future children of infer-

192. NORMAN DANIELS, JUST HEALTH: MEETING HEALTH NEEDS FAIRLY 34, 59 (2008).

193. I am hoping to avoid any metaphysical or ontological debate by framing this justice claim on behalf of children who are born as a result of infertility treatment, rather than making such a claim on behalf of "potential" children resulting from infertility treatment.

194. *See supra* notes 128–32 and accompanying text.

195. The problem of non-identity was first identified by Derek Parfit. *See* DEREK PARFIT, REASONS AND PERSONS 359 (1984). At the time the problematic decisions are made, no person exists who is being harmed. *See id.* Let us take the example of a couple undergoing infertility treatment using gonadotropins and artificial insemination. In their first treatment cycle, they develop six follicles containing eggs. This suggests a high risk for high-order multiples. They have the choice of continuing with the cycle, or canceling the cycle and undergoing an additional cycle of treatment with a lower dose of gonadatropins. The couple elects to continue with the current cycle. All six eggs fertilize and implant, resulting in sextuplets. Each of the sextuplets survives, but each is born with significant health problems. Most people's intuition is that the couple has done something wrong if they elect to continue with the cycle and thereby risk harm to their children. However, when we examine the outcome for the sextuplets (a disabled life versus non-existence), we cannot say they have been harmed. *See* Jeffrey Reiman, *Being Fair to Future People: The Non-Identity Problem in the Original Position*, 35 PHIL. & PUB. AFF. 69, 72 (2007).

196. *See, e.g.*, Rahul Kumar, *Who Can be Wronged?*, 31 PHIL. & PUB. AFF. 99 (2003).

tility treatment have a justice claim to be given a fair opportunity to be born in singleton pregnancies. This claim can be used to support an infertility mandate because insurance coverage for infertility treatment removes the financial pressure that can result in risky treatment decisions.

One might object at this point on the basis that if the risks associated with high-order multiples are a significant concern, direct regulation of infertility treatment, rather than indirect influence through insurance regulation, is the preferable course of action. For example, physicians could be legally prevented from transferring more than two embryos in a given IVF cycle, or regulations could specify when an IUI cycle needed to be cancelled. This type of regulation would in large measure control the high-order multiple problem without shifting the financing burden to the public at large. However, it is unlikely that such legislation would ever be seriously considered in the United States, where we are quite hesitant to interfere with physician autonomy.[197] There may be cases where the best clinical decision is to transfer four embryos. An insurance mandate would encourage a patient to make a different decision, but it would not prohibit the patient and her doctor from making a different choice. Direct regulation does not have the same room for clinical judgment, absent a significant waiver procedure. As a result, insurance regulation may be both more likely to occur and to provide the type of physician autonomy that Americans value.[198]

d. Summary of Justice Claims

While not purporting to provide a definitive analysis of the justice issues involved in an infertility mandate, this Part has suggested that the more compelling justice claims appear to be those of the infertile population and the children who result from infertility treatment. These stakeholders stand to gain improved access to medical treatment and improved health

197. For a discussion of physician autonomy, see HALL, *supra* note 38, at 88–91.

198. In a sense, mandating insurance coverage instead of directly regulating treatment decisions offers a form of libertarian paternalism, or what Thaler and Sunstein would call a nudge. *See* RICHARD H. THALER & CASS R. SUNSTEIN, NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS 72 (2008).

outcomes, respectively.[199] The competing claim of the population unaffected by insurance appears to be less compelling (primarily increased cost), but it is somewhat difficult to judge the magnitude of this claim. In large part, it turns on the extent to which individuals in this group actually become unable to afford health insurance as a result of an infertility mandate. The data that is available suggests that this would be a small group.[200] As a result, it appears that there is a potentially valid justice claim to be made in favor of an infertility mandate. This, together with the market problems earlier identified, suggests that an infertility mandate is justified.

4. Cost-Benefit and Cost-Effectiveness Analysis

A cost-benefit analysis determines whether the benefit obtained is worth the cost. In the medical context, this means translating clinical outcomes into monetary terms.[201] Often, cost-benefit analysis is approached by determining what individuals would be willing to pay for a given health outcome.[202] A comparison is made between the treatment cost and the willingness-to-pay for the outcome. If the willingness-to-pay is greater than the cost of treatment, there is a positive cost-benefit analysis. Unfortunately, while there are several studies regarding the willingness-to-pay for infertility treatment, each of which finds at least preliminary evidence that willingness-to-pay for infertility treatment is greater than its cost, they are limited in scope and suggest further research is necessary.[203] Therefore, while all studies appear to be positive (and even have some advantages over the cost-effectiveness analysis discussed below), there does not appear to be enough solid data to rely on a cost-benefit analysis for infertility treatment at this point.

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199. Mothers undergoing infertility treatment are also likely to benefit from improved health outcomes caused by a decrease in high-order multiple births. *See supra* notes 126–27 and accompanying text.

200. *See supra* note 180 and accompanying text.

201. Van Voorhis & Syrop, *supra* note 107, at 959.

202. *See id.*

203. *See, e.g.*, Maria Granberg et al., *Couple's Willingness to Pay for IVF/ET*, 74 ACTA OBSTETRICIA ET GYNECOLOGICA SCANDINAVICA 199 (1995); Peter J. Neumann & Magnus Johannesson, *The Willingness to Pay for In Vitro Fertilization: A Pilot Study Using Contingent Valuation*, 32 MED. CARE 686 (1994); Mandy Ryan, *Using Willingness to Pay to Assess the Benefits of Assisted Reproductive Techniques*, 5 HEALTH ECON. 543 (1996).

Cost-effectiveness analysis of infertility treatment often looks at the cost per delivery.[204] One study at the University of Iowa, based on infertility treatment provided in 1992, found an average cost of delivery of $44,200 for patients undergoing IVF.[205] The study found that a woman's age has a significant impact on the cost effectiveness of IVF.[206] For women younger than thirty-eight, the cost per delivery was $31,597.[207] For women older than thirty-eight, the cost per delivery was $89,981.[208] When compared to tubal surgery, which can help certain infertile individuals and is generally covered by health insurance, the cost per delivery for IVF was almost half that associated with tubal surgery.[209] In comparing IVF against other types of infertility treatment, this study found that non-IVF treatments had lower costs per delivery.[210] With intrauterine insemination alone, cost per delivery was $8,674; for clomiphene citrate and insemination, the cost was $7,808; and for gonadatropins and insemination, the cost was $10,282.[211] However, the cost-effectiveness of IVF is greater than other treatment options where male sperm count is low.[212] Unfortunately, this study is somewhat dated, reflecting lower-than-current IVF success rates. In addition, because the outcome measured is cost per delivery, it fails to take into account other costs, such as those associated with multiple births. As a result, there are insufficient data to rely on a cost-effectiveness argument with respect to an infertility mandate.

C. Arguments Against an Infertility Mandate

While the previous Part presented arguments in favor of an infertility mandate, this Part will briefly discuss the primary objections to an infertility mandate that fall outside of the preceding discussion. These objections are addressed separately because they are particular to an infertility mandate, rather than being applicable to mandates generally. The primary arguments against an infertility mandate are (1) that in-

204. *See* Van Voorhis & Syrop, *supra* note 107, at 960–62.
205. *Id.* at 962.
206. *Id.*
207. *Id.*
208. *Id.*
209. *Id.* at 963.
210. *Id.* at 965.
211. *Id.*
212. *Id.* at 966.

fertility treatment is not medically necessary, and (2) that the market already functions effectively to provide infertile individuals with appropriate treatment options.

1. Lack of Medical Necessity

One of the primary objections to an infertility mandate is likely to be that infertility treatment is not medically necessary. Infertility treatment is often characterized as a "quality of life" benefit, rather than a medically necessary treatment that preserves or extends life. [213] An infertile individual can lead a physically healthy life without treatment. As a result, the case for mandating coverage for infertility treatment is perhaps weak. However, this view overlooks the impact that insurance coverage for infertility treatment can have on the health of the mother, as well as on the health of children born from infertility treatment.

The issue of medical necessity is perhaps relevant in setting priorities. Many would see mandates that might extend an individual's life (for example, various cancer screenings) as higher priorities than infertility treatment. Setting priorities between treatment mandates is a difficult business that requires a systematic study of services that are covered by the standard health insurance contract, services that are not covered, and evidence supporting mandatory inclusion of services currently excluded. Under this analysis, infertility treatment will not necessarily have a low priority. For example, if one adopts Norman Daniels' approach of focusing on medical care that restores "normal species functioning," infertility should clearly be covered because reproducing is part of basic species functioning.[214] Many people would agree that the ability to bear children is important and perhaps central to well-being.[215]

213. *See, e.g.*, Leon R. Kass, *Regarding the End of Medicine and the Pursuit of Health*, *in* CONCEPTS OF HEALTH AND DISEASE: INTERDISCIPLINARY PERSPECTIVES 3, 5 (Arthur L. Caplan et al. eds., 1981) (arguing that infertility treatment aims not at the patient's health but rather at satisfying his, albeit in some cases reasonable, wishes: "They are not acts of medicine, but of indulgence or gratification, in that they aim at pleasure or convenience or at the satisfaction of some other desire, and not at health.").

214. *See* DANIELS, *supra* note 192, at 34. "For example, infertility is a departure from normal functioning that reduces an individual's fair share of the normal opportunity range and gives rise to claims for assistance on the fair equality of opportunity view . . . ." *Id.* at 59.

215. *See, e.g.*, Elizabeth A. Pendo, *The Politics of Infertility: Recognizing Coverage Exclusions as Discrimination*, 11 CONN. INS. L.J. 293, 338–40 (2005) (discuss-

There is also evidence that bearing children lowers a woman's risk of developing certain types of life-threatening illnesses.[216] In any event, it is not at all obvious that infertility is of such low importance that a mandate to cover treatment should not be seriously considered, particularly given the potential health improvements for both mother and children.

2. What Market Failure?

One might disagree with the argument that there is, in fact, market failure with respect to insurance for infertility treatment. It is widely agreed that traditional insurance coverage for infertility treatment is not generally available.[217] However, because of strong demand for infertility services and the expense associated therewith, the market has adapted by creating shared-risk plans. As previously discussed, shared-risk plans are thought to expand access to infertility treatments by protecting against the risk of failure, and are also thought to give patients a valuable signal regarding their likely chance of success.[218]

Even if one agrees that shared-risk plans serve a valuable purpose, it is hard to argue that they effectively address the market failure with respect to infertility insurance. First, shared-risk plans are available only for couples undergoing IVF. They do not cover the majority of expenses an infertile couple faces—specifically, the tests necessary to diagnose infertility as well as all treatments other than IVF.[219] Shared-risk plans may help to address negative externalities in IVF decision making, but they do not address negative externalities present in other treatment decisions. Finally, shared-risk

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ing the importance of child bearing to most individuals); Katherine T. Pratt, *Inconceivable? Deducting the Costs of Fertility Treatment*, 89 CORNELL L. REV. 1121, 1129 (2004) ("Infertility deprives would-be parents of an 'experience that is central to . . . identity and meaning in life.' " (quoting JOHN A. ROBERTSON, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES 24 (1994))).

216. For example, the risk of ovarian cancer is lessened in women who have given birth. *See, e.g.*, Nicholas D. Hollander, *Risk of Ovarian Cancer is Lessened by Childbearing, Pill Use and Hysterectomy*, 27 FAM. PLAN. PERSP. 94, 94 (1995).

217. *See* Bundorf et al., *supra* note 168, at 4.

218. See *supra* Part II.A.3. for a discussion of shared-risk plans.

219. Infertility treatments other than IVF account for the vast majority of medical treatment sought by infertile individuals. *See* Nuñez, *supra* note 93, at 61, tbl.2 (of those women who sought medical help to become pregnant, 74.3% sought medical advice, 47.72% utilized ovulation drugs, 13.66% utilized artificial insemination, and 3.15% utilized IVF).

plans are of limited value in truly expanding access, as they require a couple to pay more than the cost of a single cycle of IVF. The monetary threshold to participate is therefore likely to be prohibitively high for many patients. Shared-risk plans do not appear to rescue infertility treatment from the need of an insurance mandate.

D. A Value-Based Infertility Mandate?

Accepting the arguments in favor of adopting an infertility mandate does not finish our task but perhaps begins an even harder one. The success of an infertility mandate will lie in its details. Based on the arguments presented, the goal is to craft an infertility mandate that is cost effective, minimizes the incidence of high-order multiples, and avoids moral hazard. This might, and arguably should, include getting involved in treatment guidelines. For example, the law might set a limit on the number of cycles that will be covered, a dollar amount of total benefits that would be paid, or a significant deductible that must be satisfied. The mandate might also specify, in the case of IVF, how many embryos can be transferred or, in the case of artificial insemination, the maximum number of mature eggs that can be present prior to insemination.[220] Drafting the specifics of an infertility mandate also includes difficult boundary drawings involving marital status, donor gametes, age, and sexual orientation. This Part examines the manner in which states with infertility mandates have drawn boundaries, as well as how some foreign countries have chosen to regulate coverage of infertility treatment, in order to determine what a value-based infertility mandate might look like.

1. State Regulation: A Lack of Value-Based Provisions

For the eleven states that currently mandate infertility coverage, it is interesting to note the boundaries that they have chosen to draw.[221] Only one specifically excludes coverage of

220. Legal requirements could go even further. For example, if lawmakers wanted to address concerns about "excess embryos" from IVF cycles, they could limit the number of eggs allowed to be fertilized or mandate that a couple must either use all of the embryos created or agree to put any unwanted embryos up for adoption.

221. The following state laws mandate some form of coverage for infertility treatment: ARK. CODE ANN. § 23-85-137 (West 2007); CONN. GEN. STAT. ANN. §

IVF (the most expensive and most effective treatment), but covers less expensive, less effective technologies.[222] Another three states mandate coverage only for IVF, not for other infertility treatment options.[223] Only four states have marital status requirements.[224] Of these, three states provide coverage only for married couples who are not using donor eggs or sperm.[225] Those states that cover IVF set various limits on its usage. Several states limit coverage to a specified dollar amount: Arkansas ($15,000 lifetime maximum), Maryland ($100,000 lifetime maximum), and Rhode Island ($100,000 lifetime maximum).[226] Other states provide limits based on the number of attempts made: Connecticut (four cycles of ovulation induction, three cycles of IUI, and two cycles of IVF), Hawaii (one cycle of IVF), Illinois and New Jersey (four completed egg retrievals),[227] and Maryland (three IVF attempts per live birth).[228] States also vary in the amount of time a couple must have attempted pregnancy in order to qualify for benefits. These requirements vary from one year to five years.[229] Many

38a-536 (West 2007); HAW. REV. STAT. § 431:10A-116.5 (2007); 215 ILL. COMP. STAT. ANN. 5/356m (West 2007); MD. CODE ANN., INS. § 15-810 (West 2007); MASS. GEN. LAWS ANN. ch. 175, § 47H and ch. 176B, § 4J (West 2007); MONT. CODE ANN. § 33-31-102 (2007); MONT. ADMIN. R. 6.6.2508 (2008) (applies to HMO contracts only); N.J. STAT. ANN. § 17:48A-7w (West 2007); N.Y. INS. LAW § 3221 (McKinney 2007); R.I. GEN. LAWS §§ 27-18-30, 27-41-33, 27-19-23 (2007); W. VA. CODE § 33-25A-2 (2007) (applies to HMO contracts only).

222. *See* N.Y. INS. LAW § 3221 (McKinney 2007).

223. *See* ARK. CODE ANN. § 23-85-137 (West 2007); HAW. REV. STAT. § 431:10A-116.5 (2007); MD. CODE ANN., INS. § 15-810 (West 2007).

224. *See* 054-00-001 ARK. CODE R. §1 et seq. (2008); HAW. REV. STAT. § 431:10A-116.5 (2007); MD. CODE ANN., INS. § 15-810 (West 2007); R.I. GEN. LAWS §§ 27-18-30, 27-41-33, 27-19-23 (2007).

225. *See* 054-00-001 ARK. CODE R. §1 et seq. (Weil 2008); HAW. REV. STAT. § 431:10A-116.5 (2007); MD. CODE ANN., INS. § 15-810 (West 2007).

226. *See* 054-00-001 ARK. CODE R. §1 et seq. (Weil 2008); MD. CODE ANN., INS. § 15-810 (West 2007); R.I. GEN. LAWS §§ 27-18-30, 27-41-33, 27-19-23 (2007).

227. 215 ILL. COMP. STAT. ANN. 5/356m(b)(1)(B) (West 2007) ("[I]f a live birth follows a completed [egg] retrieval, then 2 more completed [egg] retrievals shall be covered."); N.J. STAT. ANN. § 17:48A-7w (West 2007).

228. MD. CODE ANN., INS. § 15-810 (West 2007).

229. *See* 054-00-001 ARK. CODE R. §1 et seq. (Weil 2008) (two years of unexplained infertility); CONN. GEN. STAT. ANN. § 38a-536 (West 2007) (unable to conceive or sustain a pregnancy during a one year period); HAW. REV. STAT. § 431:10A-116.5 (2007) (a history of infertility of at least five years' duration); 215 ILL. COMP. STAT. ANN. 5/356m (West 2007) (unable to conceive after one year); MD. CODE ANN., INS. § 15-810 (West 2007) (infertility of at least two years' duration); MASS. GEN. LAWS ANN. ch. 175, § 47H and ch. 176B, § 4J (West 2007) (unable to conceive during a period of one year); N.J. STAT. ANN. § 17:48A-7w (West 2007) (unable to conceive after two years if the female partner is under 35; after one year if the female partner is 35 or older); R.I. GEN. LAWS §§ 27-18-30, 27-41-

states provide an exception to these time requirements if either individual being treated has been diagnosed with a medical condition recognized to cause infertility.[230] Nearly all of the state laws cover IVF only if the individuals being treated have been unable to become pregnant or sustain a pregnancy through other, less costly treatments that are also covered by the insurance plan.[231] Only four states impose age restrictions on the mandated coverage. These restrictions range from floors of twenty-one to twenty-five years old[232] to ceilings of forty to forty-five years old.[233] Only one state (Connecticut) limits the number of embryos that can be transferred per IVF cycle (to two embryos, regardless of age).[234] No state requires coverage for homosexual couples seeking to have children through artificial insemination or IVF.

These state laws are, at least at first glance, somewhat surprising. Only seven of the states with mandates have chosen to draw "social boundaries" on the mandate, such as limiting coverage based on marital status or the use of donor gametes. No state has limited coverage based on the number of children the woman or couple already has. Several states draw "cost containment" boundaries; however, in most cases these boundaries do not appear to be drawn with cost effectiveness in

33, and 27-19-23 (2007) (unable to conceive during a period of two years). Mandated benefit laws which define infertility as the inability to attain pregnancy after a specified period of attempting to conceive make homosexual couples ineligible for benefits.

230. *See, e.g.*, HAW. REV. STAT. § 431:10A-116.5 (2007) (no passage of time required to establish infertility where it is related to endometriosis, exposure in utero to diethylstilbestrol, damaged fallopian tubes, or "abnormal male factors").

231. Of the states that specifically cover IVF treatment, only Massachusetts and Rhode Island do not specify that coverage for IVF is available only if the individual has been unable to conceive through less costly treatments covered by the insurance policy. *See* MASS. GEN. LAWS ANN. ch. 175, § 47H and ch. 176B, § 4J (West 2007); R.I. GEN. LAWS §§ 27-18-30, 27-41-33, and 27-19-23 (2007).

232. N.Y. INS. LAW § 3221 (McKinney 2007) (not required for individuals under 21 years old); R.I. GEN. LAWS §§ 27-18-30, 27-41-33, and 27-19-23 (2007) (not required for women under 25 years old).

233. CONN. GEN. STAT. ANN. § 38a-536 (West 2007) (must be younger than 40); N.J. STAT. ANN. § 17:48A-7w (West 2007) (must be 45 or younger); N.Y. INS. LAW § 3221 (McKinney 2007) (must be 44 or younger); R.I. GEN. LAWS §§ 27-18-30, 27-41-33, and 27-19-23 (2007) (must be 42 or younger). Massachusetts does not set any statutory age limits, but under regulations, does allow insurers to "establish reasonable eligibility requirements, based upon the insured's medical history." 211 MASS. CODE REGS. 37.09 (2008). Presumably this would allow insurers to set an age limit.

234. *See* CONN. GEN. STAT. ANN. § 38a-536 (West 2007).

mind.[235] Perhaps most surprisingly, given the arguments above in favor of an infertility mandate, only one state law appears to be targeted at reducing the number of high-order multiples through "treatment boundaries." The only state law that appears to be targeted to reduce high-order multiples and reflects current clinical and economic data is Connecticut's.[236] Connecticut's mandate provides per cycle limits for each of the available treatment options, and these limits appear to reflect cost-effectiveness considerations.[237] In addition, IVF is only required to be covered if no more than two embryos are transferred per cycle and the woman has not yet reached her fortieth birthday.[238] However, Connecticut, along with the majority of states mandating coverage for infertility treatment, requires the use of IUI plus gonadatropins before the use of IVF.[239]

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235. With the notable exception, perhaps, of age floors and ceilings. Young women are generally more likely to spontaneously conceive, and older women have a much more difficult time obtaining pregnancy, even with the most advanced infertility treatments. *See* AMERICAN SOCIETY OF REPRODUCTIVE MEDICINE, AGE AND INFERTILITY: A GUIDE FOR PATIENTS (2003), *available at* http://www.asrm.org/Patients/patientbooklets/agefertility.pdf.

236. *See* CONN. GEN. STAT. ANN. § 38a-536 (West 2007). The apparent lack of "treatment boundaries" can perhaps be explained by examining when these state laws were passed. Many of these mandates were passed in the late 1980s or early 1990s. *See, e.g.*, 215 ILL. COMP. STAT. ANN. 5/356m (West 2007) (passed in 1991); MASS. GEN. LAWS ANN. ch. 175, § 47H and ch. 176B, § 4J (West 2007) (passed in 1987). At that time, IVF success rates were significantly lower, and it is perhaps understandable why legislatures were not comfortable allowing patients to proceed directly to IVF. In 1995, the first year for which national statistics are available, IVF was successful in 19.6% of cycles. CENTERS FOR DISEASE CONTROL & PREVENTION, 1995 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES, NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS VOLUME I—EASTERN UNITED STATES 35 (1997), http://www.cdc.gov/art/ArchivedARTPDFs/95 eastern.pdf. In addition, the rate of high-order multiples resulting from IVF used to be much higher. In 1995, 4.5% of all clinical pregnancies achieved through IVF were triplets or greater. *Id.* at 14, fig. 8b. Connecticut's law, which does appear to be well-targeted based on clinical data, was only passed in 2005. CONN. GEN. STAT. ANN. § 38a-536 (West 2007). This would tend to support the theory that data limitations prevented earlier laws from being well-targeted. However, Rhode Island's law, passed in 2006, is similar in structure to those passed many years earlier. R.I. GEN. LAWS §§ 27-18-30, 27-41-33, and 27-19-23 (2007). Time, it appears, is not a sufficient solution.

237. *See supra* note 102. The limit of two IVF cycles is likely driven less by falling cumulative pregnancy rates after two cycles than by cost considerations. There is some evidence that cumulative pregnancy rates continue to increase even after many treatment cycles. *See, e.g.*, Shai E. Elizur et al., *Cumulative Birth Rate Following In Vitro Fertilization: A Study of 5,310 Cycles*, 22 GYNECOLOGIC ENDOCRINOLOGY 25, 26–27 (2006) (finding that cumulative pregnancy rates continued to rise through fourteen IVF cycles).

238. *See* CONN. GEN. STAT. ANN. §38a-536 (West 2007).

239. *See id.*

While IUI plus gonadatropins has been shown to be less expensive per pregnancy, it also carries with it a significant risk of high-order multiples.[240] No state mandate makes any attempt to lessen the risk of high-order multiples associated with IUI plus gonadatropins (for example, by specifying clinical guidelines that must be followed or requiring patients to consent to selective reduction prior to receiving treatment).

One lesson to take away from examining the existing state infertility mandates is that crafting sound health insurance mandates is a difficult and constantly evolving process. As medical advances are made, as success rates change, and as economic data becomes available, mandates should be amended to reflect best practices. Unfortunately, this type of attention to changing medical and economic conditions is likely to be difficult to get from legislators.

Going forward, infertility mandates should be value-based. For example, with respect to infertility treatment, reimbursement could be made contingent upon transferring no more than a specified number of embryos in an IVF cycle or cancelling an IUI cycle where more than a certain number of eggs are developing. The trade-off is explicit: society is willing to share in the costs of treatment but only if patients follow clinical best practices. If a patient wants to take what society considers to be unnecessarily high risks with respect to multiples, the patient must pay for the treatment themselves.

2. Federal Proposals

While no federal mandate for infertility coverage has been passed, such legislation has been introduced on numerous occasions.[241] The most recent federal proposal, the Family Building Act of 2007, mandates infertility coverage for all group and individual health insurance policies.[242] It defines infertility as

240. *See generally* Gleicher, *supra* note 115. Mandated coverage for IVF has been shown to decrease multiple gestation rates. *See* K.R. Omurtag & T.L. Toth, *The Cost Effectiveness and Health Outcomes of In Vitro Fertilization (IVF) as a Mandated Benefit*, 88 FERTILITY & STERILITY S122 (2007).

241. *See, e.g.*, Fair Access to Infertility Treatment and Hope Act of 2000, S. 2160, 106th Cong. (2000); Family Building Act of 2001, H.R. 389, 107th Cong. (2001); Family Building Act of 2003, H.R. 3014, 108th Cong. (2003); Family Building Act of 2005, H.R. 735, 109th Cong. (2005).

242. *See* Family Building Act of 2007, H.R. 2892, 110th Cong. (2007). The bill was introduced in the House on June 27, 2007 and referred to committee. No further legislative action has taken place. 153 CONG. REC. H7339 (daily ed. June 27, 2007) (statement of Sen. Weiner).

"the inability to conceive after 1 year of unprotected intercourse or the inability to carry a pregnancy to live birth."[243] A patient would only be entitled to IVF treatment if she has been unable to become pregnant and give birth through "less costly medically appropriate infertility treatments" that are covered by insurance.[244] The bill also imposes a cycle limit; coverage is only available for four completed egg retrievals.[245] However, if a live birth follows a completed egg retrieval, then at least two more egg retrievals will be covered, up to a lifetime maximum of six retrievals.[246] The bill contains no marital status or age restrictions, nor any restrictions aimed at reducing multiple births.[247] Being charitable, one could characterize the proposed legislation as being targeted toward increasing access to treatment while controlling costs. While it is difficult to draw too much from proposed legislation, the federal legislation does not appear well targeted to minimizing multiple births, controlling moral hazard, or supporting clinical best practices. The result is perhaps not surprising given the nature of the legislative process.

3. International Coverage

Several countries include access to infertility treatment in their national health plans,[248] although treatment parameters and regulations vary significantly. Belgium, which offers comprehensive coverage of infertility treatment, offers a unique example of tailoring regulation to best clinical practice. Belgium initiated its current coverage scheme for infertility treatment in 2003.[249] It provides coverage for up to six cycles of IVF for women who are younger than forty-two.[250] However, coverage is only provided if the patient complies with certain limitations on embryo transfer.[251] For a woman under thirty-

243. *Id.* at § 2.
244. *Id.*
245. *Id.*
246. *Id.*
247. Coverage would, however, be limited to heterosexual couples based on the definition of infertility.
248. One survey found that twenty-two countries provided at least partial coverage for assisted reproductive technologies as part of their national health plan. *See* International Federation of Fertility Societies, *Surveillance 2007, Chapter 3: Insurance Coverage*, 87 FERTILITY & STERILITY S14, S15–S16 tbl.3.1 (2007).
249. *Id.* at S14.
250. *Id.*
251. *Id.*

five attempting her first cycle of IVF, only one embryo may be transferred.[252] For her second through sixth cycle, she may have a maximum of two embryos transferred.[253] For women between the ages of thirty-five and thirty-nine, only two embryos may be transferred during the first and second cycles and, for the third cycle, no more than three embryos.[254] Between the ages of thirty-nine and forty-two, embryo transfer is unrestricted.[255] Early results reveal that the number of multiple pregnancies has been significantly reduced but not eliminated.[256] Prior to enactment of the current program, rates of multiples were approximately thirty percent and in 2005 had been reduced to ten percent.[257]

Whereas Belgium's regulation of infertility coverage is based on clinical guidelines and a desire to reduce multiple births, Italy's regulation reflects religious concerns. Italy, a predominantly Catholic country, enacted a new law in 2004 significantly restricting IVF practices within the country.[258] Under the new law, donor gametes may be not used in any infertility treatment, nor may couples use surrogate mothers.[259] Only couples who are married or in a stable relationship are eligible for treatment.[260] Regardless of how many eggs are retrieved during IVF, only three may be fertilized and all three resulting embryos must be transferred.[261] Embryos may not be frozen.[262] While one study found that the pregnancy rate per IVF cycle following the passage of the new law is not significantly different than the pregnancy rate prior to the law

252. *Id.*
253. *Id.*
254. *Id.*
255. *Id.*
256. *Id.*
257. *Id.*
258. *See Italy Fertility Treatment Curbed*, BBC NEWS, Mar. 9, 2004, *available at* http://newsvote.bbc.co.uk/mpapps/pagetools/print/news.bbc.co.uk/2/hi/europe/3545421.stm. It is the position of the Catholic Church that children should be conceived only through marital sexual intercourse. *See* Congregation for the Doctrine of the Faith, Donum Vitae, Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation (1987), http://www.ewtn.com/library/CURIA/CDFHUMAN.htm.
259. *Italy Fertility Treatment Curbed*, BBC NEWS, Mar. 9, 2004, *available at* http://newsvote.bbc.co.uk/mpapps/pagetools/print/news.bbc.co.uk/2/hi/europe/3545421.stm.
260. *Id.*
261. *Id.*
262. *Id.*

change, the transfer of a higher number of embryos in younger patients has led to a significantly higher triplet rate.[263]

Israel, on the other hand, provides generous access to infertility treatment despite the fact that some treatments are considered to be impermissible under rabbinical law.[264] Israel includes access to infertility treatment, including IVF, in its basic health care coverage and provides unlimited coverage up to the birth of two living children.[265] The coverage is available to married as well as single women, although a screening interview is required for women seeking donor insemination and is limited to women who are older than thirty but younger than fifty.[266]

These international examples give us additional perspectives on the task of boundary drawing inherent in an infertility mandate. Belgium has provided generous access to treatment but has tailored coverage to reflect clinical best practices aimed at cost effectiveness and reducing the incidence of high-order multiples. Other than age, no social restrictions appear to be used. Italy provides an example of a country not driven primarily by clinical best practices or cost-effectiveness but, rather, moral considerations. Israel provides a different model—one that, like Belgium, emphasizes access. However, despite Israel's broad access, state-provided coverage is only provided up to the birth of two living children, a significant social restriction.

4. Summary of Infertility Case Study

A much better infertility mandate could be crafted than those currently in place at the state level. Embracing a value-based mandate could both minimize the cost of an infertility mandate and increase its effectiveness. This is true not just of an infertility mandate but nearly every justified mandate. There is no doubt that difficult choices would be involved, including decisions as to who is eligible to receive treatment and

263. Paolo Emanuele Levi Setti et al., *Results of In Vitro Fertilization in Italy After the Introduction of a New Law*, FERTILITY & STERILITY (forthcoming 2008) (finding that the triplet rate among women younger than thirty-six years old increased from 0.58% to 4.71% following the law change).

264. *See* Ellen Waldman, *Cultural Priorities Revealed: The Development and Regulation of Assisted Reproduction in the United States and Israel*, 16 HEALTH MATRIX 65, 81–85 (2006).

265. *Id.* at 81–82.

266. *Id.* at 85.

what treatment an individual is entitled to receive. Nevertheless, these difficult choices must be made to improve our health care system. Two further examples of the value-based approach are provided below.

III. DIABETES CASE STUDY

Diabetes, which affects approximately seven percent of the U.S. population,[267] is "a group of diseases marked by high levels of blood glucose resulting from defects in insulin production, insulin action, or both."[268] There are three primary types of diabetes: Type 1, Type 2, and gestational diabetes.[269]

Type 1 diabetes usually occurs in children and young adults, and it results from the body's failure to produce insulin.[270] In order to survive, Type 1 diabetics must receive insulin via injection or pump.[271] Type 1 diabetes is not preventable.[272] Approximately five to ten percent of Americans with diabetes have Type 1 diabetes.[273]

Type 2 diabetes is also referred to as adult-onset diabetes. Type 2 diabetes often begins with insulin resistance, which results in cells not using insulin properly.[274] As insulin resistance continues, the pancreas loses its ability to produce insulin.[275] Type 2 diabetes is more likely to affect those who are older, obese, or physically inactive; those who have a family history of diabetes; and those who are members of certain racial and ethnic groups.[276] The vast majority of Americans with diabetes have Type 2 diabetes.[277]

Gestational diabetes is a form of diabetes that develops during pregnancy. It occurs in about four percent of all preg-

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267. American Diabetes Association, All About Diabetes, http://www.diabetes.org/utils/printthispage.jsp?PageID=ALLABOUTDIABETES_233165 (last visited Sept. 25, 2008).

268. CENTERS FOR DISEASE CONTROL & PREVENTION, NATIONAL DIABETES FACT SHEET 1 (2007), http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf.

269. *Id.*

270. *Id.*

271. *Id.*

272. *Id.*

273. *Id.*

274. *Id.*

275. *Id.*

276. *Id.* "African Americans, Hispanic/Latino Americans, American Indians, and some Asian Americans and Native Hawaiians or Other Pacific Islanders are at particularly high risk for [T]ype 2 diabetes and its complications." *Id.*

277. *See id.*

nant women in the United States.[278] "Gestational diabetes occurs more frequently among African Americans, Hispanic/Latino Americans, and Americans Indians."[279] Obesity and a family history of diabetes are also positively correlated with a diagnosis of gestational diabetes.[280] Gestational diabetes must be treated during pregnancy in order to avoid harming the infant.[281] Women who have had gestational diabetes are at increased risk for developing Type 2 diabetes following the pregnancy.[282]

Diabetes was the seventh-leading cause of death in the United States in 2006.[283] Individuals with diabetes are twice as likely to die as people without diabetes of similar age.[284] Diabetes can contribute to many other health problems (referred to as co-morbidities), such as heart disease, stroke, high blood pressure, blindness, kidney disease, nervous system disease, amputations, dental disease, and pregnancy complications.[285] Adequately controlling blood glucose levels lessens the risk of these complications.[286] As noted above, Type 1 diabetics must receive insulin in order to survive. Those with Type 2 and gestational diabetes have a variety of treatment options, including diet and exercise programs, weight loss, as well as taking oral medication and insulin when needed.[287]

Treatment of diabetes is generally covered by health insurance contracts because it is the treatment of a disease, medically necessary, generally non-experimental, and generally not specifically excluded from the contract. However, successful diabetes care involves managing the disease, not just treating its complications and consequences. Managing diabetes involves patient education, frequent monitoring of blood glucose levels, and appropriate medication.[288] Patient educa-

278. American Diabetes Association, Gestational Diabetes, http://www.diabetes.org/gestational-diabetes.jsp (last visited Sept. 25, 2008) (this results in about 135,000 cases in the United States each year).

279. CENTERS FOR DISEASE CONTROL & PREVENTION, *supra* note 268, at 1.

280. *Id.*

281. *Id.*

282. *Id.* at 1–2 ("[A]fter pregnancy, 5% to 10% of women with gestational diabetes are found to have diabetes, usually [T]ype 2. Women who have had gestational diabetes have a 40% to 60% chance of developing diabetes in the next 5–10 years.").

283. *Id.* at 9.

284. *Id.*

285. *Id.* at 10–11.

286. *Id.* at 11–12.

287. *Id.* at 2.

288. *Id.*

tion, blood glucose monitoring devices and supplies, and syringes needed for insulin injections were often excluded from health insurance contracts because patient education was not considered "medically necessary" and medical supplies typically were not covered by health insurance contracts. The American Diabetes Association has been very active and very successful in persuading states to mandate insurance coverage for education, monitoring equipment, and supplies; forty-six states currently have some form of diabetes mandate in place.[289]

A. The Case for a Diabetes Mandate

The first step in examining the case to be made for adopting a diabetes mandate is to establish a valid justification for such a mandate. First, the benefit at issue has to be one that is excluded from standard health insurance contracts. This requires careful attention with respect to diabetes, because much of the health care related to diabetes is covered by standard health insurance contracts. For example, doctor visits, lab work, and treatment of any co-morbidities would commonly be covered because they are medically necessary and non-experimental.[290] Usually, the excluded items are diabetes education, blood glucose monitors, test strips for such monitors, and injection supplies such as alcohol pads and syringes.[291] As a result, a mandate need only cover those commonly excluded items.

The strongest justification for a mandate to cover diabetes education, monitoring equipment and supplies, and injection supplies appears to be the need to address suboptimal utilization of a service. Diabetes self-management, including frequent monitoring of blood glucose levels, is a cornerstone of diabetes treatment,[292] yet evidence suggests that utilization of

289. American Diabetes Association, Commonly Asked Questions About Health Insurance, http://www.diabetes.org/advocacy-and-legalresources/healthcare/healthinsurance/faq.jsp (last visited Sept. 25, 2008).

290. *See* HAVIGHURST, *supra* note 2, at 125–37.

291. *See, e.g.*, UTAH INS. DEP'T, 2003 DIABETES MANDATE REPORT, at iii, *available at* http://www.insurance.utah.gov/2003DiabetesRpt.pdf. Such items generally fall under exclusions for medical supplies.

292. Samantha L. Bowker et al., *Lack of Insurance Coverage for Testing Supplies is Associated with Poorer Glycemic Control in Patients with Type 2 Diabetes*, 171 CANADIAN MED. ASS'N J. 39, 39 (2004); *see also* UTAH INS. DEP'T, *supra* note 291, at 16.

diabetes self-monitoring is suboptimal.[293] Evidence also suggests that utilization of diabetes self-monitoring is price elastic; when individuals do not face the full cost of monitoring, they are more likely to comply with their physician's instructions.[294] The same appears to be true of diabetes education, which has been shown to improve blood glucose levels and have other health benefits.[295] As a result, our two necessary conditions appear to be satisfied for a mandate that is aimed at increasing suboptimal utilization of a medical service.[296] However, in order for the adoption of a mandate to be justified, either a valid justice claim or a positive cost-benefit or cost-efficiency analysis is required.

Studies of diabetes mandates have found that they are cost effective[297] because they substitute low-cost intervention for

293. *See, e.g.*, Karin M. Nelson et al., *The Association Between Health Insurance Coverage and Diabetes Care; Data from the 2000 Behavioral Risk Factor Surveillance System*, 40 HEALTH SERVICES RES. 361, 361–62 (2005) (internal citations omitted); Victor G. Villagra & Tamim Ahmed, *Effectiveness of a Disease Management Program for Patients with Diabetes*, 23 HEALTH AFF. 255, 255 (2004).

294. *See, e.g.*, Karter et al., *Self Monitoring of Blood Glucose: Language and Financial Barriers in a Managed Care Population with Diabetes*, 23 DIABETES CARE 477, 477 (2000) (observing a decrease in self monitoring among individuals with higher cost sharing requirements for test strips); Bowker et al., *supra* note 292, at 42 (insurance coverage for self-monitoring supplies associated with better glycemic control than in those without such coverage). Self-monitoring costs can be $80 per month for individuals who must test frequently. KAREN POLLITZ ET AL., FALLING THROUGH THE CRACKS: STORIES OF HOW HEALTH INSURANCE CAN FAIL PEOPLE WITH DIABETES 45 (2005), *available at* http://web.diabetes.org/Advocacy/healthresearchreport0505.pdf; *see also* Bowker et al., *supra* note 292, at 39 (test strips cost approximately $1 each). *But see* UTAH INS. DEP'T, *supra* note 291, at 19 (finding that utilization of glucose monitors showed little change following a state diabetes mandate, but lancet use and urine/ketone testing strip use increased significantly, as did insulin use, syringe use, and cleaning supplies; insulin pump and insulin pump supplies also increased, but by a smaller amount).

295. *See, e.g.*, Roblin et al., *Improved Intermediate Clinical Outcomes from Participation in a Diabetes Health Education Program*, 30 J. AMBULATORY CARE MGMT. 64, 64 (2007).

296. The remaining four market problems identified in Part I do not appear to exist with respect to diabetes. Non-availability of coverage due to adverse selection should not be a problem because an insurance company should be able to determine an individual's risk of diabetes or diabetic status in a cost-effective manner. Undesired insurance company coverage determinations do not appear to be an issue with respect to diabetes and, while cognitive bias may very well result in the underestimation of diabetes risk, there is not sufficient data to use such bias as a basis for a mandate. Finally, there does not appear to be evidence that diabetes coverage is harmed by problems with the group market.

297. *See, e.g.*, The CDC DiabetesCost-Effectiveness Group, *Cost-Effectiveness of Intensive Glycemic Control, Intensified Hyptertension Control, and Serum Cholesterol Level Reduction for Type 2 Diabetes*, 287 JAMA 2542, 2546 (2002).

higher-cost treatment of diabetes complications.[298] However, a positive cost-efficiency analysis raises the question of why insurance companies do not already cover the service. As Professors Klick and Stratmann have explained, "with respect to self-management and education, if these options are effective in improving the behavior of diabetics, arguably, insurers would be likely to cover them even in the absence of a mandate."[299] "Thus, it could be the case that mandating coverage for self-management supplies and education is superfluous."[300] However, it may also be that the cost savings of a diabetes mandate accumulate over time and insurance companies do not expect to cover individuals long enough to reap the savings. It is interesting to note that some studies of the costs of diabetes mandates have found that these mandates do not significantly increase the cost of health insurance, in part because a large number of plans already cover the services at issue (presumably because of the favorable cost-efficiency analysis).[301] As a result, the value in a diabetes mandate may be in requiring the small number of insurance companies that fail to perform or recognize the cost-efficiency analysis of a diabetes mandate to cover such costs.

There may also be a valid justice claim in favor of a diabetes mandate. Those with diabetes have a claim to have their disease management costs covered. The management costs associated with other diseases are covered because such costs are typically pharmaceutical or medical in nature. The fact that diabetes management costs are primarily "supply" costs and therefore traditionally excluded from health insurance con-

298. *See, e.g.*, POLLITZ ET AL., *supra* note 294, at x; UTAH INS. DEP'T, *supra* note 291, at iii (cost of diabetes mandate "did not exceed 1[%] of losses per member per year" and did not increase comprehensive claim costs more than 0.1[%]). Some of these cost estimates are misleading because they take into account the number of plans that covered diabetes prior to the mandate. *But see* Andrew J. Karter et al., *Effect of Cost-Sharing Changes on Self-Monitoring of Blood Glucose*, 13 AM. J. MANAGED CARE 408 (2007) (finding that eliminating the copayment for diabetes testing supplies for a limited two-year period did not increase utilization or effect clinical outcomes).

299. Jonathan Klick & Thomas Statmann, *Diabetes Treatments and Moral Hazard*, 50 J. L. & ECON. 519, 524 (2007).

300. *Id.* But, preventive efforts that might be cost justified over a patient's lifetime might not be a good investment from the standpoint of an insurer. Under these conditions, it will not be possible for a given insurer to internalize the benefits of preventive care. In that case, mandates may serve as a coordination mechanism inducing insurers to cover preventive treatments that are cost justified in a social sense. *Id.* at 525.

301. *See* UTAH INS. DEP'T, *supra* note 291, at iii.

tracts (while pharmaceutical and medical costs are not) appears to be an invalid distinction. Individuals without diabetes may have a competing claim against coverage for diabetes management costs because adding coverage potentially increases the premiums for individuals who do not desire insurance against diabetes. However, given that the cost-efficiency data suggests that it is cheaper to cover diabetes management expenses than to pay for diabetes complications, this concern falls apart. Premiums for those who do not desire diabetes coverage should increase little, if at all. Having concluded that a diabetes mandate is justified, the Subpart below examines how a mandate might be structured in order to make it value based.

B. A Value-Based Mandate?

How might a value-based diabetes mandate be structured? The basic premise behind diabetes mandates appears to be that increasing self-monitoring behavior will decrease diabetes-related co-morbidities.[302] The thought is that compliance will increase as the price of self monitoring decreases. Because cost is of significant importance in the success of this mandate, it may make sense to mandate first dollar coverage (meaning coverage that is not subject to any deductible) and to limit the copayment that can be applied to diabetes testing supplies.

There are two other issues that deserve attention as well. First, diabetes education has been shown to improve health outcomes for diabetics. Devising a mandate that not only covers diabetes education, but that provides a strong nudge to actually attend a diabetes education class, would seem ideal. Doing so through insurance coverage terms is a bit difficult. One could structure the coverage so that the deductible under the plan is waived for diabetes care if the individual attends a class, but that might be too severe a punishment for those who are unable, for whatever reason, to attend a class. Instead of punishment, a reward could be made available for class attendance, such as a small cash payment.[303]

There are somewhat similar issues when it comes to encouraging Type 2 diabetics to undertake diet and exercise regimens (which, like diabetes education classes, lead to improved health outcomes). One issue that deserves attention in

302. *See id.* at iv.

303. In this way, we would be borrowing somewhat from wellness programs that seek to reward healthy behavior.

crafting a value-based mandate is the moral hazard that a diabetes mandate may create among Type 2 diabetics. Type 2 diabetes can be largely controlled or "avoided through fastidious diet and exercise regimens."[304] Without insurance coverage for the costs associated with Type 2 diabetes, there should be a strong economic incentive for those at risk of Type 2 diabetes to undertake such fastidious diet and exercise regimens. There is some evidence that the reverse is also true; insurance coverage for Type 2 diabetes may lessen the extent to which at-risk individuals engage in such preventive behavior.[305] It may also lessen the extent to which individuals already diagnosed with Type 2 diabetes undertake weight loss and exercise programs. There is again the possibility of combating this problem with either a carrot or stick approach. Under the stick approach, individuals who decline to participate in diet and exercise programs might face a higher deductible than those who enroll. The risks of this approach seem high, as there will simply be some individuals who cannot undertake such programs. The carrot approach, and that commonly used by wellness programs, would offer rewards of various kinds for participation. While such rewards certainly have their critics,[306] they may be effective in overcoming the moral hazard associated with generous insurance coverage for conditions that are partially controllable by personal actions.

Whatever the actual contours of a value-based diabetes mandate, there appears to be plenty of room for improvement. Lowering out-of-pocket costs for self-monitoring, encouraging diabetes education, and encouraging diet and exercise changes in Type 2 diabetics (and those at risk of developing the disease) should simultaneously improve health outcomes and decrease costs.

304. Klick & Statmann, *supra* note 299, at 520.

305. *Id.* at 521 (finding that diabetes "mandates generate a statistically significant increase in the [body mass indexes] of diabetics and that the effect is of practical significance").

306. *See, e.g.*, Wendy K. Mariner, *Social Solidarity and Personal Responsibility in Health Reform*, CONN. INS. L.J. (forthcoming 2008) (arguing, among other things, that such programs decrease social solidarity when they target risk factors that are more prevalent among disadvantaged populations than among those of higher socioeconomic status).

IV. AUTOLOGOUS BONE MARROW TRANSPLANT CASE STUDY

Breast cancer is the most common type of cancer diagnosed in women and is the second-leading cause of cancer deaths in women.[307] Breast cancer is treated by surgery, radiation, chemotherapy, hormonal therapy, or some combination thereof.[308] In the late 1980s, a new form of treatment for metastatic breast cancer emerged: high-dose chemotherapy with autologous bone marrow transplantation (HDC/ABMT).[309] "Autologous [bone marrow transplantation] involves extracting a patient's marrow, preserving it through a freezing process, treating the patient's cancer with [high-dose chemotherapy], and reinfusing the patient's marrow cells in the hope that the hematologic and immunological capability depleted by chemotherapy will be restored."[310] The treatment initially appeared promising, although solid clinical effectiveness data had not yet emerged.[311] Nevertheless, its use in practice became widespread.[312]

Insurance coverage for HDC/ABMT was mixed. Some insurers covered the procedure while others denied coverage on the basis that it was experimental in nature.[313] Coverage denials for the treatment resulted in a significant amount of litigation, and clinical use of HDC/ABMT continued to expand.[314] The cost of the treatment was significant, from $150,000 initially to approximately $80,000 as costs fell over time.[315] Several states passed laws mandating that insurance companies cover HDC/ABMT in order to legislatively overrule the undesired coverage determinations of the insurance companies.[316] These mandates were ill-conceived for two reasons. For one, they appeared to be based largely on anecdotes and emotion-

307. AMERICAN CANCER SOCIETY, CANCER FACTS & FIGURES 2008, at 4, *available at* http://www.cancer.org/downloads/STT/2008CAFFfinalsecured.pdf.

308. American Cancer Society, How is Breast Cancer Treated?, http://www.cancer.org/docroot/CRI/content/CRI_2_2_4X_How_Is_Breast_Cancer_Treated_5.asp (last visited Sept. 25, 2008).

309. RICHARD A. RETTIG ET AL., FALSE HOPE: BONE MARROW TRANSPLANTATION FOR BREAST CANCER 3 (2007).

310. *Id.* at 25.

311. *See id.* at 35.

312. *Id.* at 53.

313. *See id.* at 48–49, 74.

314. *Id.* at 129.

315. *Id.* at 138.

316. *See id.* at 168 (Florida, New Hampshire, Massachusetts, Virginia, New Jersey, Tennessee, Minnesota, Missouri, Georgia, Kentucky, and Montana all passed mandates).

ally-charged testimony, rather than scientific evidence.[317] In addition, by providing widespread insurance coverage for the treatment, clinical trials were hampered in their efforts to enroll patients in trials in order to establish whether the treatment was or was not effective.[318]

Eventually, clinical trial data emerged that established that HDC/ABMT is not superior to conventional treatment for breast cancer.[319] Even in the face of this evidence, it has been difficult to repeal the existing mandates for HDC/ABMT. In 2002, once the scientific evidence was clear that the treatment provided no significant benefit compared to conventional treatment, an effort was undertaken to repeal the HDC/ABMT mandate in Minnesota.[320] The repeal effort was unsuccessful.[321] Again, emotionally-charged anecdotal testimony dominated the legislative debate.[322]

Given the substantial cost of HDC/ABMT, combined with a lack of acceptable clinical evidence that it is superior to conventional breast cancer treatment, there does not appear to be a valid justification for an HDC/ABMT mandate. While legislators may want to overrule undesired insurance coverage denials for the treatment, they do so for apparently political reasons rather than for sound health policy reasons. Certainly, when considering how to craft a value-based HDC/ABMT mandate, it becomes clear that this cannot be done absent clinical effectiveness data. HDC/ABMT mandates, then, are an example of a mandate that should be repealed.

Waiting until solid evidence of clinical effectiveness is available prior to passing a mandated benefit law undoubtedly means that some individuals will lose out on promising treatments. However, clinical trials help to reduce that risk, and the trials provide the data needed to justify a mandate.. Passing mandates prior to evidence of clinical effectiveness both creates the possibility of huge amounts of inefficient medical spending and also impairs the ability of clinical trials to enroll patients.

317. *See id.* at 169–74 (describing the legislative debate in the Minnesota mandate).
318. *Id.* at 206–07.
319. *Id.* at 249–50.
320. *Id.* at 174.
321. *Id.*
322. *Id.* at 175.

CONCLUSION

The task of determining which medical risks should be compulsorily shared is a daunting one, involving considerations not just of market conditions and economics, but also fundamental issues of justice and clinical effectiveness. Even where a convincing case for a mandate can be made, crafting that mandate so that it creates the desired coverage, economic incentives, and treatment outcomes is a difficult and constantly evolving task.

Legislatures seem ill suited to these tasks.[323] Having Platonic guardians make these decisions might be the best option,[324] but a second-best solution might be to establish an independent body of health care experts who, given certain specified parameters, could make the difficult, technical decisions regarding when a substantive health care mandate is justified.[325] We could leave our current financing and delivery system in place but have uniform, national guidance on what services and treatments must be covered. In doing so, the advantages of market competition would (mostly) remain in place, but market failures, public health concerns, and injustices could be rectified in an efficient manner.

With relevant data becoming more and more available and accessible, this Article has argued that mandated benefit laws can be significantly improved by being tailored to the specific problem the mandate is trying to address. These value-based mandates will retain the important policy functions of mandated benefit laws while improving their effectiveness and efficiency. Not only will mandated benefit laws be improved, but our health care system will be able to test whether value-based rationing might benefit the system as a whole and be an important contributor to health care reform.

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323. *See* Korobkin, *supra* note 17, at 80–83.

324. David A. Hyman, *Health Insurance: Market Failure or Government Failure?*, CONN. INS. L. J. (forthcoming 2008) (manuscript at 8, on file with author).

325. *See* Korobkin, *supra* note 17, at 74–75, 83–87; *see also* HALL, *supra* note 38, at 73–76.