Economic Implications of Potential Changes to Regulatory and Reimbursement Policies for Medical Devices

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OBJECTIVE: To evaluate the impact of regulatory scenarios on the financial viability of medical device companies.

DESIGN: We developed a model to calculate the expected net present value of a hypothetical product throughout preclinical development, clinical testing, regulatory approval, and postmarketing. We tested 3 scenarios: (1) the current regulatory environment; (2) a scenario in which medical devices are subject to the same evidence standards required for pharmaceuticals; and (3) a scenario consistent with the Coverage with Evidence Development: Coverage with Study Participation (CSP) policy proposed by the Centers for Medicare and Medicaid Services, whereby Medicare will pay for beneficiaries to receive new devices that are not currently determined to be “reasonable and necessary” if the patients participate in clinical studies or registries.

MEASUREMENTS AND MAIN RESULTS: When applying assumptions consistent with the implantable cardioverter-defibrillator market, the net present value at the start of development was an estimated $553 million in the current regulatory environment, $322 million in the pharmaceutical scenario, and $403 million in the CSP scenario. Sensitivity analyses showed that the device industry would likely be profitable in all 3 scenarios over a range of assumptions.

CONCLUSIONS: The environment in which the medical device industry operates is financially attractive. Furthermore, when compared with the alternative of applying the same evidence standards for pharmaceuticals to medical devices, the CSP policy offers improved financial incentives for medical device companies.

KEY WORDS: device approval; health policy; medicare; reimbursement

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INTRODUCTION

Since the inception of the Medicare program, reimbursement for products and services has been based on whether these are considered “reasonable and necessary for the diagnosis or treatment of illness or injury”.1 However, as rapid advances in health care technology continue to drive medical costs upward, it has become increasingly difficult for the Centers for Medicare and Medicaid Services (CMS) to balance its dual responsibilities of protecting the Medicare trust fund, while simultaneously enhancing the welfare of beneficiaries—particularly when it comes to coverage decisions for costly new medical devices.2

The level of evidence supporting the safety and efficacy of medical devices is typically less than that available for pharmaceutical products.3 For high-risk devices or new devices for which there is no comparator product on the market (class III devices), manufacturers must submit a premarket approval application to the Food and Drug Administration (FDA), from which regulators determine whether there is sufficient evidence of safety and effectiveness for the intended uses.4 In practice, this standard is often met by small clinical trials in select groups of patients. The studies often do not employ randomized designs, and the FDA generally does not require manufacturers to collect long-term efficacy data.5–7 Although there have been improvements in study designs over recent years, and experts have called for increased standardization for medical devices, the FDA Modernization Act of 1997 requires that the FDA allow manufacturers to use the least burdensome means available to demonstrate safety and efficacy.8

From the perspective of device manufacturers, increasing the amount of clinical evidence required for approval or reimbursement would create a barrier to market entry. Manufacturers argue that the device industry is fundamentally different from the pharmaceutical industry in terms of organization size and access to capital, and that the engineering framework supporting continuous device innovation stands in contrast to the pharmaceutical industry’s focus on the development and testing of drugs. At the same time, the US medical device industry is estimated to be a $74.5 billion enterprise,9 with substantial firms having dominant positions in critical markets. Thus, the challenge for CMS is to craft a standard for the reimbursement of medical devices that both protects patient safety and preserves the incentive structure that has spurred growth and innovation in the device industry.

To address these and other issues, CMS has proposed the “Coverage with Evidence Development” policy, which includes “Coverage with Appropriateness Determination” (CAD) and “Coverage with Study Participation” (CSP).10 In the context of devices, the purpose of CAD is to collect additional data to document that the use of a device accords
with Medicare’s coverage criteria. Under CSP, if CMS determines that the information necessary for a coverage determination is not available, Medicare will reimburse for new devices only if patients enroll in clinical studies or registries supported by the developers of the technologies or other related groups.11–13 With these data, Medicare will be better positioned to make evidence-based determinations of whether new devices are “reasonable and necessary”.14

Although device manufacturers are likely to resist mandates to collect additional data or other requirements that add uncertainty to the reimbursement process, it is also likely that the CSP strategy would be more economically attractive than a policy requiring manufacturers to provide the higher level of evidence usually required of pharmaceutical products in approval and reimbursement decisions. In this paper, we use a simple model to evaluate the financial viability of a hypothetical company developing a new class III medical device in 3 regulatory scenarios that reflect different policy approaches to this issue.

## METHODS

The model calculates the expected net present value (NPV) of a new device throughout preclinical development, clinical testing, regulatory approval, and postmarketing. The NPV of a project is the sum of the present values of all cash flows related to the project, both negative (costs) and positive (revenues).15 Firms commonly use NPV calculations to evaluate investment opportunities by explicitly incorporating a stated rate of return that reflects the cost of capital to the firm (known as the discount rate). These discount rates can reflect the availability of capital to the firm, the risk of the investments undertaken by the firm, or even the stage of the investment. In risky endeavors like drug development, in which firms can accrue costs for several years before receiving revenues, future revenues are discounted heavily in the calculation of NPV.

Our model focuses on the NPV of a product at the beginning of the first year of its development (year 1). For simplicity, and to evaluate threshold levels, we dichotomized this measure: If the expected NPV in year 1 is positive, investment in the device is considered economically attractive; if the expected NPV is negative, the company or its investors will be better off directing capital to other investments. (However, if capital or management resources are constrained, the firm would focus on projects with the greatest possible return for a given level of risk.)

### Regulatory Scenarios

The 3 regulatory scenarios of interest are national coverage policies that we have termed the “current scenario”, the “CSP scenario”, and the “pharmaceutical scenario”. The current scenario reflects the current regulatory environment for class III medical devices, in which the level of evidence necessary for FDA approval is less than that required for pharmaceuticals. In this scenario, we assume that CMS will provide payment for a device if it is approved by the FDA, but will not provide payment for the device while it is undergoing clinical testing before approval. In the CSP scenario, CMS will reimburse for the device but will require Medicare beneficiaries who receive the device to be enrolled in a clinical trial or registry. Finally, in the pharmaceutical scenario, CMS will require that the process of developing clinical evidence to justify coverage for a class III medical device is as rigorous as the current FDA approval process for pharmaceutical products.

The structure of our evaluative model is based on the expected life cycle of the device. Compared to pharmaceutical products, it is often difficult to discern when the life cycle of a device begins and ends, because most devices are developed in an incremental fashion. In our model, we assumed that preclinical development of a new device takes approximately 3 years. We assumed that it would take 2 years to complete clinical studies in the current and CSP scenarios and 3 years in the pharmaceutical scenario (Table 1).16 For all 3 scenarios, we assumed that CMS is making a national coverage determination, and that it takes the FDA and CMS a total of 1 year to make approval and coverage decisions.17,18 Also, because there are fewer regulatory hurdles slowing the entry of other device manufacturers to market, we assumed that the period during which the product can recoup the cost of development is 3 years after clearance from the FDA.

Table 2 summarizes the assumptions of each regulatory scenario. As a starting point, many of the inputs in the model were based on the implantable cardioverter-defibrillator market; however, the model can be applied to numerous medical devices through the use of sensitivity analysis. In the base-case analysis, we assumed that the probability of FDA approval and CMS coverage for the device is 90% in the current scenario. We applied the same probability to represent the likelihood that CMS would require patients to be enrolled in a registry for the CSP scenario. In the pharmaceutical scenario, we assumed that if the required trial(s) revealed that the device is efficacious, CMS would provide coverage. Otherwise, it would not. We performed extensive sensitivity analyses to evaluate the impact of changes to model parameters and to calculate break-even.

### Table 1. Device Life Cycle under Three Regulatory Scenarios

| Scenarios     | Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---------------|------|---|---|---|---|---|---|---|---|---|----|
| Current       | Preclinical development | Clinical testing | FDA/CMS review | Sales (90%) | — |
| CSP           | Preclinical development | Clinical testing | FDA/CMS review | CSP (90.0%) | Sales (68.5%) | — |
| Pharmaceutical| Preclinical development | Clinical testing | FDA/CMS review | Sales (68.5%) | — |

FDA: Food and Drug Administration; CSP: Coverage with Study Participation.
values that correspond to the point at which NPV in year 1 is equal to zero in each scenario.

**RESULTS**

In the base case, estimates of NPV in year 1 were $8553 million in the current scenario, $8403 million in the CSP scenario, and $322 million in the pharmaceutical scenario, indicating that development of a new device is an economically attractive investment in all 3 scenarios.

In each scenario, device manufacturers spent an estimated $60 million on preclinical development over 3 years. They spent an estimated $18.6 million over 2 years on clinical testing in the current and CSP scenarios, and $74.4 million over 3 years in the pharmaceutical scenario. After a 1-year

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**Table 2. Assumptions in the Base-case Analysis**

| Assumption | Current Scenario | CSP Scenario | Pharmaceutical Scenario |
|------------|------------------|--------------|-------------------------|
| Annual cost of preclinical development* | $20 million | $20 million | $20 million |
| FDA-mandated studies | | | |
| Number of patients | 600b | 600b | 2,4007 |
| Cost to device company per patientd | $25,000 | $25,000 | $25,000 |
| CSP studies | | | |
| Number of patientsa | – | 20,000 | – |
| Cost to device company per patientf | – | 81,000 | – |
| Probability that the device is truly effectiveg | 0.685 | 0.685 | 0.685 |
| Probability of CMS coverage (traditional or CSP) after FDA approval | 0.900h | 0.900h | 0.685i,1 |
| Probability of CMS coverage after CSP periodj,1 | – | 0.685 | – |
| Patients per year who will receive the device after FDA and CMS approvalj | 25,000 | 25,000 | 25,000 |
| CMS payment for the device during CSP periodb | – | 25,000 | – |
| CMS payment for the device after CMS coverage approvalb | $25,000 | $25,000 | $25,000 |
| Cost to the device company of manufacturing the devicef | $86,000 | $86,000 | $86,000 |
| Duration of preclinical development, y* | 3.00 | 5.47 | 5.32 |
| Annual cost of preclinical development, $ | $20 million | $223.8 million | $168.7 million |
| Assume that 90% of devices are approved by the FDA. |
| Assume that no type 1 or type 2 errors would occur. |
| Estimate based on 64,000 implantable cardioverter defibrillators inserted in 2003, 3 major manufacturers of the devices, and the majority of patients as Medicare beneficiaries. |
| Consistent with recommendations from the International Conference on Harmonization, which suggest that premarket clinical safety databases include 1,500 patients for chronic medications intended to treat non-life-threatening conditions, we assumed that 2 randomized controlled trials with 600 patients per arm are needed for FDA approval in the pharmaceutical scenario. |
| Assume that 20% of patients would choose not to enroll in trials or registries under the CSP policy. |
| Based on the probability that investigational drugs proceeded from phase 3 testing to marketing approval. |
| Assume that the per-patient cost for CSP incurred by the device company would be significantly lower than costs for clinical trial participation. |

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**Table 3. Sensitivity Analyses: Parameter Values When NPV=0**

| Variable | Base-case estimate | Current scenario | CSP scenario | Pharmaceutical scenario |
|----------|-------------------|-----------------|--------------|-------------------------|
| Annual cost of preclinical development, $ | 20 million | 223.8 million | 168.7 million | 138.6 million |
| Duration of preclinical development, y* | 3.00 | 5.47 | 5.32 | 5.04 |
| Probability that device is truly effectiveg | 68.5 | NA | NA | 16.7 |
| Probability of CMS coverage in current model, % | 90 | 9.8 | NA | NA |
| Patients receiving device each year after FDA clearance, nj | 25,000 | 2,709 | 3,038 | 6,083 |
| CMS payment (price) for device, $8 | 25,000 | 7,152 | 10,299 | 15,951 |
| 1-year market life | 2,709 | 3,038 | 6,083 |
| 2-year market life | 3,743 | 6,011 | 8,142 |
| 3-year market life | 2,619 | 4,266 | 5,650 |
| 4-year market life | 2,061 | 3,381 | 4,429 |

CSP: Coverage with Study Participation; FDA: Food and Drug Administration; CMS: Centers for Medicare and Medicaid Services; and NPV: net present value.

*Without varying total life cycle (i.e., with 5 years for clinical development, only 1 year after FDA clearance in each scenario).

†NPV in year 1 is positive at all probabilities. In the current scenario, NPV remains constant under the assumption that evidence is not generated (by trials or through provider experience) to demonstrate ineffectiveness. In the CSP scenario, sufficient sales are generated during the 2 years during CSP to maintain positive NPV regardless of the probability of true effectiveness.

‡In the base-case CSP scenario, 20,000 patients received the device each year during the CSP period, and 25,000 patients received the device each year after FDA clearance. In the break-even analysis, we assumed that the same number of patients received the device in both periods.

§We maintained the assumption that the cost of goods sold is equal to 24% of the price of the device.
period for FDA and CMS review, expected revenue from CMS for coverage of the device was an estimated $562.5 million per year for 3 years in the current scenario, with the cost of goods estimated at $135 million per year, resulting in net total cash flow of $1.28 billion over 3 years. In the CSP scenario, CMS was estimated to pay $450 million per year for the 2 years during the CSP period and $428 million in the last year of the device’s marketable life, with coverage provided by the traditional mechanism. After subtracting the cost of manufacturing the device and the cost of implementing CSP, the net total cash flow was an estimated $973 million. Finally, in the pharmaceutical scenario, annual revenues were an estimated $428 million per year, with the cost of the devices estimated at $103 million per year, resulting in net cash flow of $976 million.

**Sensitivity Analysis**

Starting with the base-case assumptions for the current scenario, sensitivity analyses showed that payment could be

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**Figure 1.** Net present value in year 1 by annual cost of preclinical development

**Figure 2.** Net present value in year 1 by probability that the device is effective
as low as about $2,600 per device and still allow the NPV to
break even at 80 (Table 3). Payment could be as low as $4,266
per device in the CSP scenario and as low as $5,650 per device
in the pharmaceutical scenario to allow the company to
maintain a break-even NPV.

The base-case assumption of $20 million in annual costs or
$60 million in total costs for preclinical development may be an
overestimate for devices that represent incremental improve-
ments over existing products, resulting in conservative estimates
of NPV; however, this estimate may be too low for new devices. In
sensitivity analysis, we found that the annual cost of preclinical
development could be as high as $223.8 million per year in the
current scenario, $168.7 million per year in the CSP scenario,
and $138.6 million per year in the pharmaceutical scenario to
maintain a positive NPV (Fig. 1 and Table 3).

We also varied the probability that the device would be
found truly effective in more extensive clinical testing, as
required in the CSP and pharmaceutical scenarios. Given that

Figure 3. Net present value in year 1 by number of years the device is on market after FDA clearance

Figure 4. Net present value in year 1 by number of years of active market life at a price of $5,000 and $2,500 per device
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DISCUSSION

Our findings suggest that the CSP policy is preferable to a system in which clinical testing for devices is held to the evidence standards currently applied to pharmaceuticals. With CSP, the device industry would benefit from earlier revenue streams generated by the initiation of Medicare coverage for products after relatively limited clinical testing, as compared to delayed revenue streams when products are subject to more rigorous premarket clinical testing.

Sensitivity analyses revealed that the medical device industry is likely to be profitable in all 3 regulatory and reimbursement scenarios over a range of assumptions of lower or higher research and development costs, shorter or longer product cycles, lower or higher prices, and smaller or larger markets. In addition, the assumptions used in our base-case analysis were conservative. For example, we estimated the undiscounted cost of clinical trials to be relatively high in the pharmaceutical scenario, at approximately $874 million—an amount approaching the $825 million estimate for investigational pharmaceutical products.16,18 We also assumed that the market life for the device was just 3 years after FDA clearance. And we made the conservative assumption that all FDA-approved devices would be subject to the CSP policy in the CSP scenario. In practice, we expect that the probability will be less than 1, even for class III devices. Although application of CSP is in its early days, it is clear that medical devices will not be exempt. Of the 6 national coverage determinations currently affected by the CED policy, 2 pertain to medical devices (implantable cardioverter-defibrillators and cochlear implants).

The medical device industry is a heterogeneous mix of small new ventures and large mature firms. Larger firms would have the capital necessary to develop a medical device and conduct more rigorous randomized trials to evaluate safety and efficacy, whereas smaller firms may not. Our findings reflect an expected NPV derived from multiplying expected revenues by the probability that firms would receive those revenues. Given that many smaller firms may not be able to sustain a negative approval or coverage decision, the stakes are higher on an individual device basis. That is, although the expected NPV is positive, a lower probability of coverage by CMS will cause a number of small firms to drop out of the marketplace or force them to partner sooner with larger development firms, reducing expected returns to their investors. The ensuing impact on the productivity of research and development across the industry is unknown. It is possible that firms and venture capitalists will become more risk-averse in funding the development of innovative medical devices, or they may selectively inhibit the development of products targeted at smaller patient populations or those with high hurdles to reimbursement.

Although our model is largely hypothetical, it can be used to help shape a discussion of the benefits and tradeoffs to the device industry under various reimbursement models. Nonetheless, some limitations must be considered. First, although we included an estimate of the cost of manufacturing the product, our analysis does not include costs to device companies for sales, marketing, and administration. An accounting of these costs can be considered by reducing reimbursement for the product by an estimate of the percentage of total sales that would be allocated for these activities. For example, in the current scenario, 67% of sales of the product could be allocated to such expenses while allowing the firm to maintain a positive NPV in year 1. In the CSP and pharmaceutical scenarios, costs for sales, marketing, and administration could be as high as 63% and 57% of sales, respectively, to maintain a positive NPV in year 1. Another limitation is that we did not adjust the cost of capital for the inherent risk of each stage of the research program or additional issues that may affect postapproval uptake of the product. One such issue is whether payments to providers are sufficient to cover the device and associated costs. In some cases, CMS grants additional reimbursements for new technologies through add-on payments for inpatient services, new technology pass-through, or new ambulatory payment classifications for outpatient services. However, this process can take considerable time.

Although we believe our model provides a useful framework for thoughtful discussion about the financial risks imposed on the device market by various regulatory scenarios, the model does not fully address other important issues. One is the value of having high-quality information about risks and benefits of devices after more rigorous clinical testing. Another is the potentially lower risk of adverse events, although this is
incorporated in our application of a lower probability of a device moving to the sales phase in the CSP and pharmaceutical scenarios. Finally, because the model inherently reflects the perspective of the device industry, it does not incorporate effects on consequent health care spending or the social costs and benefits associated with approving or halting new medical devices.

Overall, our findings substantiate beliefs that, for some markets, the environment in which the medical device industry operates is financially attractive. Furthermore, our analysis shows that when compared with the alternative of applying the same evidence standards for pharmaceuticals to medical devices, the CSP policy offers improved financial incentives for medical device companies.

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