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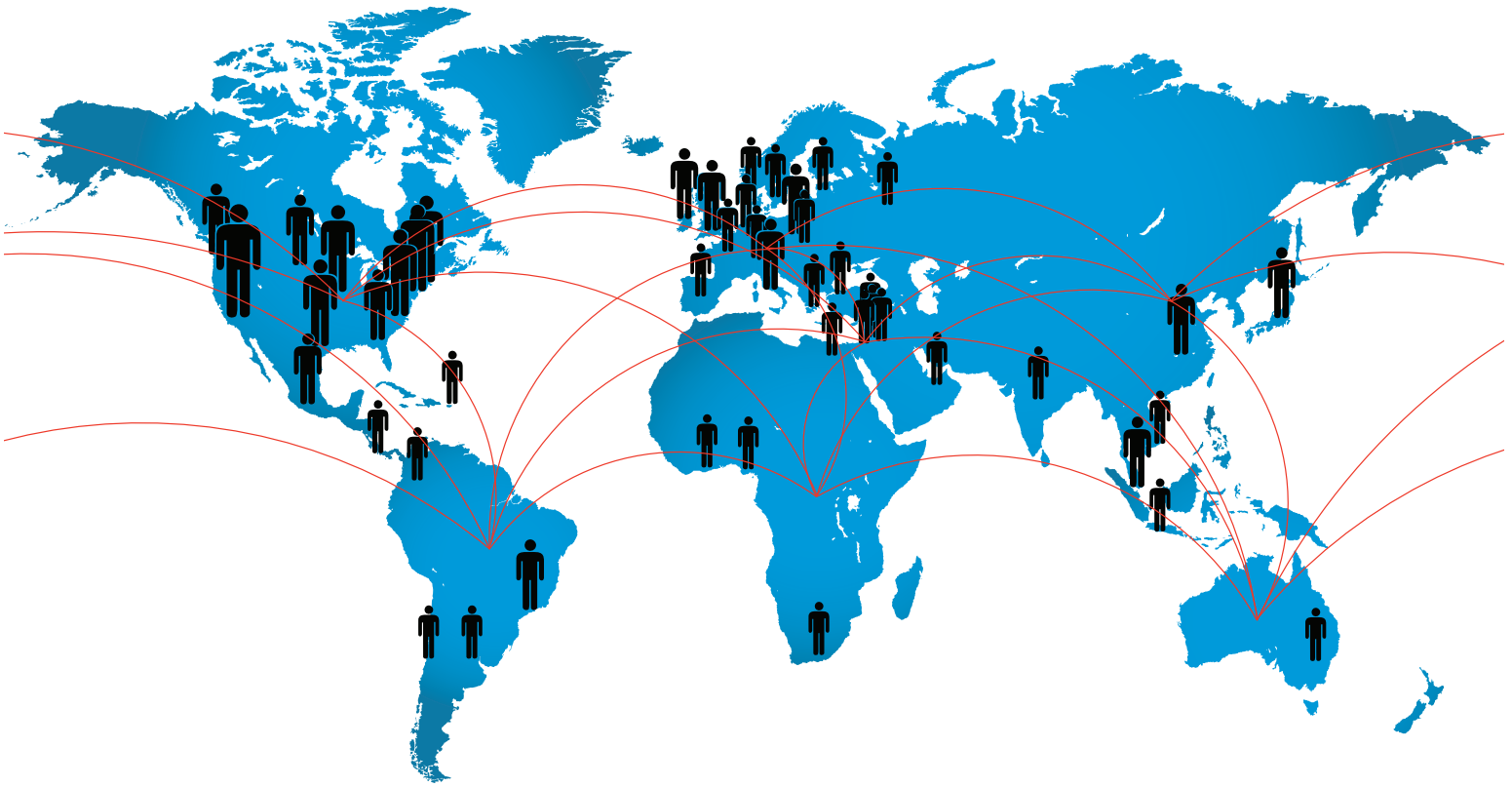

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Jumpstarting Medical Device Innovation: New Incentives Create VC Opportunities

Anh Nguyen

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Historically, medical device investment in the United States has been seen as uncertain within both the regulatory pathway through the U.S. Food and Drug Administration (FDA), as well as reimbursement by the Centers for Medicare and Medicaid Services (CMS). Nonetheless, the U.S. medical device market remains the world's largest, with revenues estimated at $125.4 billion in 2013,[1] and projected to grow at a CAGR (compound annual growth rate) of 6.1% over the 2013–2018 period.[2]

As medical devices become increasingly complex and are expected to "do more" with regard to health impact, investment requirements for new technology have skyrocketed: it takes $31 million to bring a low-to-moderate risk device to market, and $75 million for a higher-risk device.[3] Thus, to minimize investment costs and avoid regulatory hurdles, the majority of medical device development and clinical trials are now performed outside the United States.

Early-stage venture capital is a key element required to translate new knowledge into successful diagnostics and therapies. VC finances the work needed to identify platforms (hardware, software) or products (a lead molecule or medical device prototype) and develop them to the proof-of-concept stage. At the early-investment stage, however, there is great uncertainty over whether the technology is safe and effective, whether the regulatory standards (to which clinical trials and reimbursement are designed) will remain stable, and what the likelihood might be for the large follow-on investments needed for commercial development.

Regulatory and reimbursement policies have a profound impact on the amount of capital and the types of life science projects that investors pursue.[4] The uncertainty with regulatory and reimbursement headwinds, especially during this

[1] PMPA, *Business Trends 2014 Review and Summary* (20 January 2015), para. 4, http://www.pmpa.org/docs/default-source/reports2/business-trends-report-december-2014.pdf?sfvrsn=0.

[2] Espicom, "The Medical Device Market: USA," 12 December 2014, first bullet point, http://www.espicom.com/usa-medical-device-market.html.

[3] Josh Makower, Aabed Meer, and Lyn Denend, *FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Device Companies* (November 2010), http://advamed.org/res.download/30.

[4] Jonathan Fleming, "The Decline Of Venture Capital Investment in Early-Stage Life Sciences Poses a Challenge to Continued Innovation," *Health Affairs* 34, no. 2 (2015): 271–76. doi:10.1377/hlthaff.2014.1051.

decade, has led to an investor drought within the medical device arena—which raises serious concerns for innovation in a new healthcare economy.

Technological innovation is widely recognized as a key determinant of economic and public health progress,[5] and it is widely understood that medical discoveries and advancements to treat and cure diseases through innovative medical devices and combination products could—and should—be reaching U.S. patients more efficiently. Time to market and cost must decrease, without lessening the standards of safety and efficacy. Observing the trend to outsource medical device development and testing, the U.S. government has sought ways to reduce barriers to innovation by improving collaboration for innovators with and between federal agencies.

In this article I provide a brief historical context for the 2014 CMS regulation change, outline a new pathway for additional (non-dilutive[6]) funding to innovators for clinical trials, and describe a template to evaluate a product's clinical value by regulators, payers, hospitals, and providers. With non-dilutive premarket funding and standardized methods to share clinical data, investors and innovators can invest with greater security and also streamline medical device innovation.

Medical Device Innovation in the United States: Historical Context[7]

In 1995, the FDA and CMS entered into an interagency agreement: the FDA agreed to categorize clinical trials, called *investigational device exemptions* or IDEs, for Medicare coverage (i.e., non-dilutive funding).[8] The resulting regulations created a path to Medicare coverage under certain circumstances.[9] At the time, however, coverage and payment decisions were made by local Medicare contractors (consistent with general CMS coverage policies), and were applicable only to the clinical trial items and services within the Medicare contractor's particular jurisdiction.

These processes for determining coverage of IDE devices and clinical trials have been inefficient and burdensome, and have created variability that makes it difficult for sponsors to obtain Medicare coverage for national IDE clinical studies.[10] Local Medicare contractors have applied various levels of scrutiny to IDE study protocols, used different review processes, and sometimes made coverage decisions on a claim-by-claim basis. According to CMS, this has led to inconsistent IDE coverage across Medicare contractors.

The U.S. healthcare system has historically suffered from a paradox in which effective products are used in ineffective ways, because of fragmented organization and misaligned payment incentives for both physicians and hospitals.[11] As new devices are released, their makers must overcome three major hurdles before the products reach patients:

[5] David Cutler, "The Determinants of Mortality," *Journal of Economic Perspectives* 20, no. 3(2006): 97-120. doi:10.1257/jep.20.3.97.

[6] Non-dilutive funding is financing that does not require the sale of the company's shares, and hence does not cause dilution of the existing shareholders; it can provide critical cash to support a company's development.

[7] See Amy Belt, "Reimbursement Buzz Saw," *Kauffman Fellows Report* 1 (2010):15-23, http://www.kauffmanfellows.org/journal_posts/reimbursement-buzz-saw/.

[8] The process was codified in regulations at 42 C.F.R. § 405.201 et seq., which describe two categories of investigational devices, labeled A and B. Category A devices are "experimental," where the "absolute risk" of the device type has not been established and the FDA is unsure whether the device type can be safe and effective. This category typically encompasses only FDA Class III devices. Category B devices are "non-experimental," where the "incremental risk" is the primary risk in question, that is, underlying questions of safety and effectiveness of the device type have already been resolved. FDA Class I, II, or III devices may fall within this category.

[9] Medicare coverage became possible for Category B ("non-experimental") devices and for the costs of routine items and services related to clinical trials for both these and Category A ("experimental") investigational devices. Category A devices themselves are not eligible for Medicare coverage.

[10] Matthew Lester and Rebecca Scott, "Results of Huron's Coverage Analysis Policy Survey," slides presented as part of Huron Life Sciences Clinical Research Management Webinar Series, 30 May 2012, slides 38-40, https://www.huronconsultinggroup.com/~/media/Insights-Media-Content/PDF/Clinical-Research-Billing-Survey-Presentation.pdf.

[11] Sabriya Rice, "Inside Medicine's Gray Zone," *Modern Healthcare*, 24 January 2015, http://www.modernhealthcare.com/article/20150124/MAGAZINE/301249987/inside-medicines-gray-zone.

- documenting safety and efficacy to the FDA's satisfaction[12];
- convincing insurers that the product should be covered under the definition of medical necessity; and
- motivating physicians to prescribe their use.

Of those three hurdles, technology firms have focused on the FDA and insurers as the most difficult, relying on fee-for-service payment methods to ease purchasing discussions among providers and hospitals.[13]

Although market access and insurance coverage remain important priorities, a significant new challenge to the medical technology industry is the change in payment methods to physicians and hospitals.[14] Newer, bundled payment methods now incentivize hospitals and providers to care about both the types and the costs of the products they use.

This change toward bundled payment is meant to shift financial responsibility regarding cost—from the insurer to the provider.[15] Technology firms within the device industry will therefore be exposed to constant downward price pressures on their products. The technology firms will then be forced to (a) provide clear value to justify their product's cost, (b) reduce both the sales cost and the development costs of their product, or (c) do both. Because of the uncertainty associated with future bundled payment models, the valuations for many emerging medical technologies are at risk, which lowers available investment and shortens investment timelines. Development of breakthrough medical products is a "long game"; thus, medical device innovators and investors should aggressively seek non-dilutive funding sources earlier in the product life cycle. The revised CMS regulations provide such access to capital.

My Role in the Regulation Change

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) allowed Medicare payment of the routine costs of care furnished to Medicare beneficiaries in certain categories of Investigational Device Exemption (IDE) studies. Covering the costs in these IDE studies removes a financial barrier that could otherwise discourage beneficiaries from participating. However, this program was quite underutilized because it was poorly known and poorly executed; essentially, innovators and investors ended up leaving money on the table.

My work as an FDA medical officer included writing policy guidance for medical devices, research into health IT and robotic systems, and scientific due diligence for emerging medical technologies. As the first Kauffman Fellow from the federal government, my interest was in the intersection between life science investment and federal regulation and reimbursement. This interest led to work as a medical officer at CMS, performing coverage analyses for both healthcare products and services (i.e., helping the government decide whether to pay for new medical breakthroughs) as part of the FDA/CMS Innovation Pathway program. With a dual role at both the FDA and CMS, I was able to identify mutual data needs between the agencies regarding requirements to perform clinical trials. By structuring and sharing clinical trial designs, simultaneously with both agencies ahead of time, innovators avoid duplicative or extraneous work during product development and save time and costs both before and after FDA approval.

The results of this work culminated in revised regulations that offer greater transparency for investors and innovators regarding medical product regulation and reimbursement, as well as opportunities for non-dilutive clinical trial funding.[16]

[12] James Robinson, "Providers' Payment and Delivery System Reforms Hold Both Threats and Opportunities for the Drug and Device Industries," *Health Affairs* 31, no. 9(2012):2059-67, doi:10.1377/hlthaff.2012.0401.

[13] Amit Kukreja and Matias Gonzalez, "MedTech Market Access Hurdles are a Global Problem," *Medical Device and Diagnostics Industry*, 25 March 2014, http://www.mddionline.com/article/medtech-market-access-hurdles-are-global-problem.

[14] Rebecca Paradis and Erin Bartolini, "A Bundle of Potential and Risk: Bundled Payment and Its Impact on Innovation,"*NEHI Issue Brief*, November 2014, http://www.nehi.net/writable/publication_files/file/bundled_payments_issue_brief_formatted.pdf.

[15] Jeffrey D. Eyestone, *Key Trends in Healthcare Patients Payments* (J.P. Morgan, 2013), 2, https://www.jpmorgan.com/directdoc/JPM-KeyTrends-in-HealthcarePatientPayments.pdf.

[16] Centers for Medicare and Medicaid Services, "Medicare Coverage Related to Investigational Device Exemption (IDE) Studies," 5 January 2015, http://www.cms.gov/Medicare/Coverage/IDE/index.html.

Overview of the New CMS Regulations

In its update to the Physician Fee Schedule for calendar year 2014, CMS implemented major revisions to its regulations governing Medicare coverage of investigational devices, and of the routine items and services furnished to beneficiaries during the clinical studies or trials (conducted under the FDA IDE regulations).

Centralized Review

CMS has proposed a transparent, centralized review process that it expects will be more efficient because it will reduce the burden for stakeholders interested in conducting nationwide trials. Once the IDE coverage process is centralized, a single entity at CMS would make IDE coverage decisions, which would eliminate the need for duplicate review by local Medicare contractors.

The new CMS regulations unify FDA and CMS data needs in the context of prospective clinical trials for medical devices. By structuring a clinical trial simultaneously between the agencies, CMS will pay for the majority (if not all) of an FDA-approved medical device trial. The new regulation also offers much more transparency into the CMS evaluation process regarding clinical trials.

Incorporating concepts from these CMS regulations offers investors a pathway for non-dilutive funding to innovators, and can provide a data platform to evaluate a product's clinical value, both pre- and post-market, which will aid reimbursement in a future bundled-payment system. In addition, having clinical trials that collect the information needed by CMS can demonstrate clinical and economic value to private payers, hospitals, and providers. As the following section demonstrates, providing non-dilutive premarket funding and standardized methods to share clinical data (demonstrating value) offers opportunities for investors and innovators to speed medical device innovation.

New, Improved Standards for Investigational Device Coverage

CMS is committed to ensuring that Medicare beneficiaries who volunteer to participate in studies are adequately protected, and that study designs address questions of importance to Medicare and its beneficiaries.[17] To that end, CMS has created standards for clinical trials or studies evaluating Category A (experimental) or Category B (investigational) IDE devices. Medicare will cover the costs of "routine care items and services" in Category A and B trials. Additionally, CMS will cover the costs of Category B IDE devices themselves if the following standards are met:

1. The principal purpose of the study is to test whether the device improves health outcomes for appropriately selected patients.
2. The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
3. The study results are not anticipated to unjustifiably duplicate existing knowledge.
4. The study design is methodologically appropriate, and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.
5. The study is sponsored by an organization or individual capable of successfully completing the study.
6. The study is in compliance with all applicable federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812; and 45 CFR part 46.
7. Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if

[17] Although an item or service may be considered "reasonable and necessary" when used by a clinician for the benefit of an individual patient, CMS believes that it may not necessarily be reasonable and necessary when used in the context of an IDE clinical study or trial. Also, there are numerous studies and trials that may be considered "scientifically valid," but are of little benefit to Medicare beneficiaries.

the disease or condition being studied is life-threatening and the patient has no other viable treatment options.

8. The study is registered with the National Institutes of Health's (NIH) website, ClinicalTrials.gov, which is maintained by the National Library of Medicine (NLM).
9. The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes, and states that the release should be hastened if the study is terminated early.
10. The study protocol describes how Medicare beneficiaries may be affected by the device under investigation, and how the study results are (or are not) expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status is explicitly described.

CMS has also defined a new pivotal description for Category A or B clinical trials designed to collect definitive evidence of the safety and effectiveness of a device for a specified intended use, typically in a statistically justified number of subjects. Additionally, superiority studies are those intended to demonstrate (at some pre-specified level of confidence) that the effect of an investigational treatment is superior to that of an active control—by more than a pre-specified margin.

If the trial is pivotal, meets all 10 of the new criteria, and has a superiority study design, CMS will expedite decisions to cover the costs of routine care items and services in the clinical trial. According to CMS, meeting these pivotal and superiority study design criteria assures that the study results will be informative for beneficiary choices and medical decision-making in the non-trial settings where most care is actually furnished (i.e., a real world setting).

Recommendations for Medical Device Investors and Entrepreneurs

Investing in healthcare innovation necessitates a system-wide understanding of the stakeholders and institutions involved in advancing innovation: the FDA, CMS, private payers, providers, industry, and academia. Increasingly, investors will need to initiate collaboration between the innovator and other stakeholders; successful investors will be those who can actively find, facilitate, and grow synergies between these stakeholders throughout a product's development cycle.

The primary roadblock for investors and innovators to date has been a lack of understanding of both FDA and CMS requirements in the design of clinical trials. Innovators and investors need to work on clear, two-way communication—and effective expectation-setting—with the applicable government agencies in order to mitigate clinical trial uncertainties and minimize delays. By improving a pathway to communication, innovators will be able to streamline clinical trials to align with FDA-CMS needs, and thus improve the pathway from approval to reimbursement.

These recent CMS regulation revisions are of particular interest to innovators who develop medical device clinical trials, as all may now be candidates for some level of Medicare coverage. These changes are also vital to investors, medical device manufacturers, healthcare providers, and medical centers who may find the updated CMS regulation to be a pathway for new revenues.

Using the CMS framework creates value transparency—not only making non-dilutive funding easier to apply for premarket, but also providing a method to demonstrate clinical and economic value after FDA marketing approval. If understood and utilized early, the new regulation allows innovators to (a) structure a development plan that aligns FDA and CMS requirements, (b) provide non-dilutive funding for clinical trials, (c) reduce development costs, and (d) generate post-market data that can be used to demonstrate clinical results and value to hospitals and providers. Ultimately, these factors will play an increasingly

important role in a healthcare future that relies upon evidence-based clinical processes and bundled payment models.

The U.S. healthcare system will feature increasingly integrated organizations, aligned incentives, and evidence-based clinical processes. Financial rewards to medical device technology firms will be based upon the ability to collaborate with regulatory bodies, reimbursement agencies, and provider networks, in order to continuously provide and demonstrate clinical/economic value in an efficient manner.

Ten or fifteen years from now, the landscape of biomedical innovation will be vastly different (see also Dan Janiak, p. 6). New concepts in data science and analytics, wearable technology, 3D printing, precision medicine, synthetic biology, human-machine interfaces, and the Internet of Things will profoundly change the future of diagnostic and therapeutic medical products. As these ground-breaking technologies become increasingly blended into the medical product industry, many of them will need a big jumpstart through collaboration during the regulatory and reimbursement pathway, to reduce uncertainty and review times by the FDA and CMS. The high risk–high reward nature of the life science industry requires earlier collaborations with federal agencies, which then allow greater transparency for investors and innovators into the regulatory-reimbursement process, as well as providing both push incentives (i.e., reduced research and development costs) and pull incentives (i.e., smoother and better reimbursement rates). The revised CMS regulations provide new pathways to spark innovation over the coming decade.

Anh Nguyen

Anh Nguyen, MD, MBA, serves as a senior fellow on the U.S. Senate Committee on Health, Education, Labor, & Pensions, drafting legislation to strengthen and secure U.S. biomedical innovation. An anesthesiologist at the National Institutes of Health (NIH), Nguyen was previously a medical officer for the U.S. Food and Drug Administration (FDA) and Medicare (CMS), specializing in health IT and medical products. Prior to public service he was co-founder of a mobile health software technology company. Kauffman Fellow Class 17.
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Table of Contents for *Kauffman Fellows Report* Volume 6

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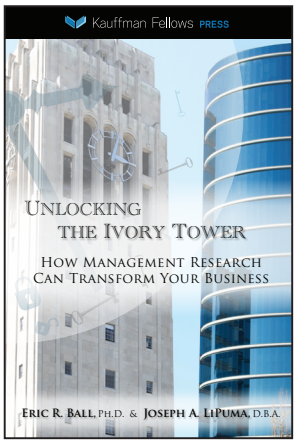

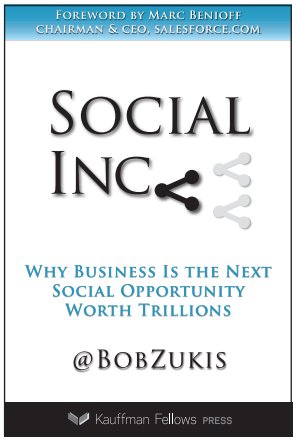

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