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Cover Page Footnote

* Assistant Professor of Business Law & Ethics and Research Coordinator in the Center for the Business of Life Sciences, Kelley School of Business, Indiana University. Research support was provided by Ken Burleson. Thoughtful feedback at early stages in this project's development was provided by Zoltan Tar. Ken Pimple generously offered engaging and valuable contributions throughout the writing of this paper. I am grateful to all three, and especially so to Julie Kadish for the invitation to participate in this Symposium issue.

THE PEOPLE'S NIH? ETHICAL AND LEGAL CONCERNS IN CROWDFUNDED BIOMEDICAL RESEARCH

JOSHUA E. PERRY, JD, MTS*

Abstract

Over the last decade, online crowdfunding has become a mainstream source of capital formation for a range of artistic and entrepreneurial endeavors. Low-barrier websites such as Kickstarter and IndieGoGo that fund production of a movie or recording of an album, in addition to charity conduits such as Kiva that facilitate the dissemination of microloans in the developing world, are trusted fundraising mechanisms that offer alternatives to traditional financing through banks and venture capitalists. Moreover, these models predicated on the solicitation of relatively modest amounts of money create a more egalitarian investment environment wherein donors can join the effort—and often receive some token reward in exchange for a sense of personal engagement and affiliation with the underlying project being financed. Crowdvesting is a kind of crowdfunding designed to raise capital à la traditional stock offerings and the sale of securities. Unlike charitable donations, such investment opportunities trigger analysis under existing securities laws and regulations, some of which date to post-Great Depression concerns, i.e., the 1933 and 1934 Securities Acts and others flowing from the more recent Great Recession milieu, i.e, the JOBS Act of 2012 and related state analogues. Given the decreasing availability of federal research funding, biomedical researchers have begun to explore the potential for crowdfunding models of financing. This paper explores the ethical and legal issues triggered by the specific case of the physician-researcher, active both in the clinic and at the bench, who seeks to raise funding via crowdfunding channels. Should physician-researchers solicit research funding from their patients? What are the implications for the patient's sense of trust and the patient's relationship with the physician? And what about those donating who are not patients or related stakeholders, but rather interested and sympathetic donors who wish to help the cause? This paper maps the landscape of these questions and concerns, and lays the groundwork for future empirical and theoretical explorations, as well as policy and practice guidelines.

^{*} Assistant Professor of Business Law & Ethics and Research Coordinator in the Center for the Business of Life Sciences, Kelley School of Business, Indiana University. Research support was provided by Ken Burleson. Thoughtful feedback at early stages in this project's development was provided by Zoltan Tar. Ken Pimple generously offered engaging and valuable contributions throughout the writing of this paper. I am grateful to all three, and especially so to Julie Kadish for the invitation to participate in this Symposium issue.

Introduction

Melissa Anderson Sweazy makes independent, short films. When she recently needed \$8000 to fund her latest project, "The Department of Signs and Magical Intervention," she launched a campaign on www .IndieGoGo.com to solicit donations from her friends and family.¹ The campaign launched on April 25, 2014, and ended a month later on May 25. She raised over \$11,000 from individuals who donated money in exchange for a mention in the film's credits, an appearance on screen as an extra, or a prop skateboard ridden by the main character. These token tangibles, however, were not the primary motivation for most donors. Rather, Ms. Sweazy was offering to the public an intangible opportunity to become an insider on a unique and exciting creative project. In reality, her IndieGoGo appeal was intended to reach mostly just friends and associates with a personal connection to her or the project. Perhaps random individuals might hear about the project through social media and be moved enough by the film's premise to share their personal resources, but the thrust of the fundraising effort relied on tapping into the sympathetic emotions and indie film passions of those in Ms. Sweazy's sphere of influence.

To promote and organize her fundraising efforts, Ms. Sweazy could have chosen www.Kickstarter.com, the much larger and better-known source for crowdfunding of creative projects such as films, music, and video game development. Launched in 2009, The New York Times called Kickstarter "the people's NEA," because of its democratizing effect on the landscape of grant funding and public support for the arts.² She chose IndieGoGo, however, because Kickstarter had denied a previous request to establish a campaign for an earlier project. It turns out that Kickstarter has greater internal oversight and protections for potential investors than does the upstart IndieGoGo, where a campaign to fund virtually any idea can be launched immediately without internal review.3

Jim Olson, who holds an MD-PhD, treats cancer patients at Seattle Children's Hospital, researches brain tumors at the Fred Hutchinson Cancer Research Center, and teaches at the University of Washington. He was also the subject of a profile in the July 2014 issue of Wired Maga-

The Department of Signs and Magical Intervention, IndieGoGo, https://www.indie gogo.com/projects/the-department-of-signs-and-magical-intervention (last visited July 19, 2014).

^{2.} Rob Walker, The Trivialities and Transcendence of Kickstarter, N.Y. Times (Aug. 5, 2011), http://www.nytimes.com/2011/08/07/magazine/the-trivialities-and-transcen dence-of-kickstarter.html?pagewanted=all&_r=0.

^{3.} Philip H. Kim, TMI: Honest Claims and Risk of Overdisclosure in Crowdfunding Campaigns, paper abstract submission to the Crowdfunding Conference at the University of Colorado-Boulder on file with author ("Unlike Kickstarter, Indiegogo does not have an internal approval process."). While Indiegogo does feature a "no gatekeeper" approach, dubious campaigns have prompted a "comprehensive fraud protection system to protect [its] users." James Robinson, As More Experts Dispute GoBe's "Bullshit" Medical Claims, Indiegogo Still Refuses to Pull Its Near-\$1m Campaign, PANDODAILY (Mar. 31, 2014), http:// pando.com/2014/03/31/as-more-experts-dispute-gobes-bullshit-medical-claims-indiego go-still-refuses-to-pull-its-near-1m-campaign/ (last visited March 13, 2015).

zine.⁴ According to the story in Wired, Dr. Olson had an idea several years ago for a concoction he calls "Tumor Paint," the purpose of which is to identify all of the malignant cells in a patient's body and the main ingredient of which is a molecule found in the stinger of the deathstalker scorpion. Such an exotic ingredient proved too outlandish for traditional biomedical research-funding organizations, such as the National Institutes of Health ("NIH"), a unit of the U.S. Department of Health and Human Services that makes available the largest source of medical research funding in the world via a rigorously competitive system of peer-reviewed grants.⁵ Dr. Olson instead turned to a crowdfunding model and asked his pediatric cancer patients and their families to fund his untested idea involving fluorescent scorpion toxin.⁶ Similar to Ms. Sweazy's strategy, Dr. Olson's pursuit of biomedical research funding focused on his relationships with patients and his "steady bedside manner" that had "always been much appreciated by the families of Olson's patients," who had "long expressed their gratitude by supporting his research."7

As frustration mounted in the face of failed attempts to secure grants for his chlorotoxin research, "parents upped their fundraising efforts," and Olson "embraced their generosity."8 In fact, assured by early donors "that they would go to any length" to make sure Olson received the necessary funding, he expanded his fundraising appeals to additional families.9

For parents who had witnessed their children confront the limits of cancer surgery, Olson's chlorotoxin pitch was particularly persuasive.¹⁰

Among them was Kris Forth, whose son, Brandon, had multiple surgeries to remove a tumor on his brain's fourth ventricle. "There was always a piece of the cancer left inside him," says Forth, who was by Brandon's bedside when he died in March 2010 at the age of 11. "If Tumor Paint had been available then, it probably would have changed the outcome." As part of her healing process, she opened a thrift store that has given tens of thousands of dollars to Olson's lab; an informational poster about Tumor Paint hangs by the shop's cash register.¹¹

After quickly raising \$5 million, Dr. Olson's "Tumor Paint" is currently in Phase I clinical trials. 12 Dr. Olson's crowdfunding, however, was not accomplished via the well-established, internally-regulated Kick-

^{4.} Brendan I. Koerner, One Doctor's Quest to Save People by Injecting Them With Scorpion Venom, Wired Magazine, July 2014, at 96.

^{5.} See NIH Almanac, NAT'L INST. OF HEALTH, http://www.nih.gov/about/almanac/ (last visited Nov. 28, 2014).

^{6.} Koerner, *supra* note 4, at 98.
7. *Id.* at 103. For example, Koerner reports that "[s]hortly after Olson founded his Fred Hutchinson lab in 2000, for example, a few parents banded together to host chili cook-offs and golf tournaments to raise money for staff salaries."

^{8.} Id. at 103.

^{9.} Id.

^{10.} Id.

^{11.} Id.

^{12.} Id.

starter or the upstart, decentralized IndieGoGo. Rather, Dr. Olson's online biomedical research fundraising tool was a custom-created website called Project Violet, a "philanthropic effort to drive early drug discovery at Fred Hutchinson Cancer Research Center," which, along with "certain investigators," has "equity interests." 13

While the Olson illustration appears—at least at this point in time—to be a story of successful entrepreneurial innovation in the funding of biomedical research, I argue that crowdfunding in this context triggers a number of ethical and regulatory issues that deserve careful consideration by professional societies and policy makers. Part I of this article presents a brief background on crowdfunding. In Part II, I explore the ethical differences between the contexts in which Ms. Sweazy and Dr. Olson used the crowdfunding model of fundraising. Specific issues I explore include the inevitable trading upon trust that (ideally) gets established in the physician-patient relationship; the concomitant potential for raising false hope in the context of emotionally vulnerable patients and patients' family members—who may have compromised judgment; and the ever-present conflicting interests and zealous optimism of researchers/physicians who must find a way to balance their personal career/financial/publication pressures with the best interests of patients.

Part III moves beyond the ethical considerations to explore the legal and regulatory issues raised by crowdfunding of biomedical research. Many of the issues to be explored in the legal sections flow from the Jumpstart Our Business Startups ("JOBS") Act,14 Title III of which provides a crowdfunding exemption from securities registration, as well as its state-based analogs that have recently passed in many state legislatures.

Ultimately, if a researcher/physician/entrepreneur can raise money while avoiding regulatory scrutiny, this opens up the possibility of terrible abuses, including exploitation of patients and widespread fleecing of unsuspecting donors, which again triggers nontrivial ethical considerations. This article attempts to fill a gap in the literature in terms of the particular legal and ethical issues triggered by crowdfunded biomedical research, particularly when the researcher is also a clinician and the funding appeals are being made directly to the clinician's patients and their family, and to shine a critical light on this new frontier.

I. What is Crowdfunding?

Crowdfunding, 15 i.e., funding from the crowd, is generally understood to be an approach to fundraising that seeks a large number of

^{13.} Project Violet, https://www.projectviolet.org (last visited July 1, 2014).

^{14.} JOBS Act, Pub. L. No. 112-106, sec. 302(a), § 4(a)(6), 126 Stat. 306 (2012) (codified at 15 U.S.C. § 77d(a)(6) (2012)).

^{15.} A similar term, crowdsourcing, refers to distribution of smaller, discrete responsibilities for the purpose of accomplishing some large objective. The term "crowdsourcing" was apparently first used by Jeff Howe and Mark Robinson in the June 2006 issue of

contributors—often recruited and organized via online social media networks—to donate money to a specific project. Heralded as "a revolutionary and democratic way to connect ordinary individuals with innovative projects," crowdfunding efforts aimed at specific projects have been traced back at least as far as the funding of the Statute of Liberty's pedestal in the late $1800s^{18}$ and, of course, the art of seeking small donations from large numbers of people has "been the backbone of the American political system since politicians started kissing babies." The power of crowdfunding in the internet age lies in its simplicity and accessibility.

Another way of thinking about crowdfunding is to compare it to crowdsourcing or the open source movement in software development where any developer in the online community can improve software with added features and functionality.²⁰ As Nikki Pope has documented, these online communities of shared interests have proven to be hubs for the creation of products and services arising out of shared interests.²¹ Threadless is an impressive example.²² In 2000, two individuals with a desire to begin a t-shirt business founded Threadless, an online community that solicited t-shirt designs and allowed Threadless community members to vote on their favorite designs. Winning designers received free t-shirts, and community members were permitted to

Wired magazine. Paul Belleflamme et al., Crowdfunding: Tapping the Right Crowd, 29 J. Bus. Venturing 585, 588 n.3 (2014). Perhaps the clearest example of crowdsourcing is Wikipedia, "an entire encyclopedia consisting of articles written and edited by the general public." C. Steven Bradford, Crowdfunding and the Federal Security Laws, 2012 Colum. Bus. L. Rev. 1, 27 (2012).

- 16. Thomas Lee Hazen, Crowdfunding or Fraudfunding? Social Networks and the Securities Laws—Why the Specially Tailored Exemption Must be Conditioned on Meaningful Disclosure, 90 N.C. L. Rev. 1735, 1736 (2012); Belleflamme et al., supra note 15, at 588 ("Crowdfunding involves an open call, mostly through the Internet, for the provision of financial resources either in the form of donation or in exchange for the future product or some form of reward to support initiatives for specific purposes."); Meredith B. Cross, Dir., Div. of Corp. Fin., U.S. Sec. and Exch. Comm'n, Testimony on Crowdfunding and Capital Formation, available at http://www.sec.gov/news/testimony/2011/ts091511mbc.htm (Crowdfunding "is used to describe a form of capital raising whereby groups of people pool money, typically comprised of very small individual contributions, to support an effort by others to accomplish a specific goal.").
- 17. Sean M. O'Connor, Crowdfunding's Impact on Start-Up IP Strategy, 21 Geo. MASON L. Rev. 895, 895 (2014).
- 18. Anjanette H. Raymond & Abbey Stemler, Trusting Strangers: Dispute Resolution in the Crowd (unpublished manuscript) (on file with author) (citing BBC News, The Statue of Liberty and America's Crowdfunding Pioneer, Apr. 24, 2013, http://www.bbc.com/news/mag-azine-21932675) ("The Statue of Liberty campaign resembles a modern online crowdfunding effort in several impressive ways: the speed with which the money was raised, the number of small donations, and the fact that the whole process was managed by one agent the newspaper.").
- 19. Jeff Howe, Crowdsourcing: Why the Power of the Crowd is Driving the Future of Business 253 (2008).
- 20. Nikki D. Pope, Crowdfunding Microstartups: It's Time For the Securities and Exchange Commission to Approve a Small Offering Exemption, 13 U. Pa. J. Bus. L. 973, 975–76 (2011). See generally Howe, supra note 19, at 8 ("Crowdsourcing had its genesis in the open source movement in software.").
 - 21. See Howe, supra note 19, at 8; Pope, supra note 20, at 977.
 - 22. Howe, *supra* note 19, at 2.

purchase directly from Threadless. Six years after its launch, Threadless saw revenues of \$17 million.²³

With crowdfunding, "[a] nyone who can convince the public he has a good business idea can become an entrepreneur, and anyone with a few dollars to spend can become an investor."²⁴ Such egalitarian access has generated growth at a rapid rate.²⁵ Crowdfunding websites raised \$2.7 billion in 2012, an 81% increase over the previous year's fundraising totals.²⁶ According to Massolution, a crowdfunding research firm, more than 800 crowdfunding platforms are either active or planning to launch.27

Contemporary, internet-based crowdfunding efforts can be usefully categorized by the primary basis of the transaction: (1) pure donations without anything received by the donor; (2) peer-to-peer lending with or without interest recouped by the investor; (3) donations received in exchange for a nominal gift/reward or advance opportunity to purchase the product being created - but without the offer of any equity in the business; and (4) crowdvesting, or traditional investment opportunities offering an equity share of future profits.²⁸ The pure donation sites look and act like traditional charitable organizations with donors receiving nothing tangible in return. These sites—often administered by nonprofit entities or political candidates—constitute approximately 28% of the online crowdfunding marketplace.²⁹ Contributors often have no expectation of receiving anything in return for their donation. Peer-to-peer lending sites, such as Kiva.org, capitalize on the power of the crowd to fund entrepreneurs and economic development. One of the largest entities in this space, Kiva, uses a microfinancing model to collect small amounts of money to finance entrepreneurial endeavors in the developing world.³⁰ Kiva donors do not receive interest on their loans.³¹ Rather, the incentive is the knowledge that donors are providing "safe, affordable access to capital to those in need" and

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^{24.} Bradford, supra note 15, at 10. Whether or not one who contributes to a crowdfunded campaign is an investor for purposes of securities law is an analysis that will be more relevant to the questions I will explore in Part III.

^{25.} See Kendall Almerico, Crowdfunding Growing at a Startling Rate, New Report Says, Entrepreneur (June 11, 2014), http://www.entrepreneur.com/article/234426 (noting crowdfunding's growth is doubling at nearly ten times the rate of Moore's Law).

^{26.} Kylie MacLellan, Global Crowdfunding Volumes Rise 81 Percent in 2012, REUTERS (Apr. 8, 2013, 12:32 PM), http://www.reuters.com/article/2013/04/08/us-crowdfund ing-data-idUSBRE9370QY20130408.

^{27.} See Massolution, http://www.massolution.com (last visited Oct. 13, 2014).

^{28.} Id. at 14-27. See also Belleflamme et al., supra note 15, at 586 (Crowdfunding investments "can take the form of equity purchase, loan, donation, or pre-ordering of the product").

^{29.} Belleflamme et al., supra note 15, at 588 (citing an industry report at Crowdsourcing.org from 2012).

^{30.} How Kiva Works, the Long Version, KIVA, http://www.kiva.org/about/how/evenmore (last visited Mar. 13, 2015).

^{31.} Id.

thereby helping these people "create better lives for themselves and their families." ³²

Referenced in the Introduction, the most common crowdfunding platform is the donation solicited in exchange for a nominal gift or reward or advanced access to the product being created.³³ Kickstarter and IndieGoGo are the two largest reward/pre-purchase crowdfunding sites.³⁴ Each of these online communities allow entrepreneurs to present their ideas and solicit funds for the development of artistic projects or commercial products in need of financial backing.³⁵ Typically, donors receive some award or perk in exchange for their financial support, while the online platform charges a hosting fee in the form of a percentage of funds raised.³⁶

Often referred to as "enterprise crowdfunding"37 or "crowdvesting" to distinguish it from models based on donations or lending arrangements, crowdfunding that provides an equity interest, i.e., a right to a share in future derivative profits, would appear to be as simple and straightforward as the other online crowdfunding models. Because of federal securities laws, however, it is not. The Securities Act of 1933 and subsequent legislation was passed in response to the Great Depression and intended to increase disclosure and market stability.³⁸ These laws require a company to comply with complex and expensive regulatory restrictions governing the advertisement and sale of equity stakes in companies.³⁹ The advent of crowdfunding, however, has generated much new legislation in recent years. On April 5, 2012, President Barack Obama signed the Jumpstart Our Business Startups Act (the "JOBS Act"), which includes the "Capital Raising Online While Deterring Fraud and Unethical Non-Disclosure Act (the "CROWDFUND Act").40 Additionally, twelve states have passed and fourteen states (plus the District of Columbia) currently have pending legislation creating state-specific, intra-state exceptions to permit small businesses and entrepreneurs to tap into the crowd in search of invest-

^{32.} About Us, KIVA, http://www.kiva.org/about (last visited Oct. 13, 2014).

 $^{33.\}$ Id. Approximately 43% of all crowdfunding platforms are based on this prepurchase or reward model.

^{34.} Bradford, *supra* note 15, at 16. Since its launch on April 28, 2009, Kickstarter has raised \$1.4 billion from over 5 million individuals to fund over 74,000 projects. *Frequently Asked Questions, Kickstarter Stats*, Kickstarter, http://kickstarter.com/help/stats (last visited Dec. 1, 2014). IndieGoGo does not provide similar data.

^{35.} Raymond & Stemler, supra note 18.

^{36.} See Zachary J. Griffin, Crowdfunding: Fleecing the American Masses, 4 J.L. Tech & Internet 375, 380 (2013) ("For example, when Josh Freese, the former Nine Inch Nails drummer, sought funding for a new album, he offered a combination of reward and prepurchase benefits to potential contributors. If someone contributed \$50 to the new album, they would receive a 'CD/DVD set, T-shirt, [and] a '[t]hank you' phone call from Josh.").

^{37.} O'Connor, *supra* note 17, at 897–98.

^{38.} Abbey R. Stemler, The JOBS Act and Crowdfunding: Harnessing the Power—and Money—of the Masses, 56 Bus. Horizons 271, 272 (2013).

^{39.} Id.

^{40.} Id. at 271.

ments to finance their business ventures.⁴¹ These legislative developments and their applicability to biomedical research are explored further in Part III.

II. ETHICAL CONCERNS IN THE REALM OF BIOMEDICAL RESEARCH

Writing over a decade ago, Kenneth Pimple attempted to bring a measure of coherence to the field of research ethics. 42 Recognizing the complexity of subject matter encompassing "ageless moral truths and recent arbitrary conventions; minute details of particular actions and the broad sweep of public policy; life-and-death issues and matters just the other side of simple etiquette," Pimple proposed a series of three questions to be asked of any research product or project:

- Is it true?
- Is it fair?
- Is it wise?⁴³

With regard to the first question, Pimple was asking whether the data and conclusions reported by the researcher corresponded to reality. In other words, had the researcher conducted "good science?" 44 As for the fairness inquiry, Pimple was pressing on the particular dynamics of social relationships within the world of research. Into this category he placed "issues such as relationships among researchers (authorship and plagiarism); between researchers and human subjects (informed consent); between researchers and animal subjects (animal welfare); and relationships between researchers, their sponsoring institutions, funding agencies, and the government."45 The final question is meant to prompt reflection on the relationship between the research agenda and the broader social dynamics. Imbedded in the wisdom inquiry is a series of concerns regarding unintended consequences for good or ill that might flow from the research. In short, to qualify as responsible research conduct, the outcome must be a better world and/or an improved human condition.⁴⁶

Taking the specific case of Jim Olson's crowdfunded research on the use of deathstalker scorpion venom to illuminate cancerous tumors

^{41.} States that have passed crowdvesting legislation, as of July 1, 2014, include Alabama, Colorado, Georgia, Idaho, Indiana, Kansas, Maine, Maryland, Michigan, Tennessee, Washington, and Wisconsin. See e.g., Summary of ENACTED Intrastate Crowdfunding Exemptions (as of July 2014), http://www.crowdcheck.com/sites/default/files/Summary% 20of%20Intrastate%20Crowdfunding%20Exemptions_0.pdf (last visited Oct. 1, 2014). States with pending legislation include Alaska, Arkansas, California, Connecticut, Illinois, Kentucky, Missouri, New Mexico, New Jersey, Pennsylvania, South Carolina, Texas, Utah, Virginia, and the District of Columbia. Florida and North Carolina have rejected crowdvesting legislation.

^{42.} Kenneth D. Pimple, Six Domains of Research Ethics: A Heuristic Framework for the Responsible Conduct of Research, 8 Sci. & Eng'g Ethics 191, 198 (2002).

^{43.} Id. at 192-93.

^{44.} Id. at 192.

^{45.} Id.

^{46.} Id. at 193.

for purposes of surgical removal,⁴⁷ each of Pimple's three questions prompt important considerations. The first question is impossible to answer in the absence of follow-up research and validation studies, but the fact that Olson's lab findings are now being tested in Phase 1 clinical trials suggests a preliminary conclusion that indeed the science is good. The second inquiry—in the context of crowdfunding solicited from families of current and former patients—is more complex because it raises a complicated concern arising from the relational dynamics between physician and patient—and particularly what the patient views as fair. 48 The third question regarding the wisdom of the enterprise touches in this context on the broader implications of these practices, as well as how individual or public health harms can be avoided or mitigated and the benefits justly allocated. Whatever harm or wrong, if any, comes from Dr. Olson's enterprise will be small compared to the consequences of a large-scale, laissez-faire approach permitting the unchecked proliferation of similar projects. The time to consider the future and the social and scientific implications of crowdfunded biomedical research is now.

In their groundbreaking in-depth interview study of medical patients and what they can teach us about everyday ethics of healthcare, Larry Churchill, Joe Fanning, and David Schenck define "being a patient" simply as "being in a relationship with a practitioner." This ethically-complex relationship, rooted in vulnerability and trust, is ultimately bounded by a sense of fairness. ⁵⁰

Fairness here is about recognizing and respecting the roles and responsibilities the partners in doubled-agency carry as they come together with the intent of healing the patient. Fairness in this sense always has multiple dimensions. Patients may treat clinicians unfairly, they may violate the trust of that relationship by using the clinician to access controlled substances or by refusing to follow the guidance of the clinicians on matters essential to the patient's healing. In turn, clinicians may treat patients unfairly and may violate their trust by engaging them primarily as consumers and feeunits, or by ignoring patient concerns and questions.⁵¹

It is here that the crowdfunding appeal flowing from physician to patient prompts concern. As the *Wired* story explains, when traditional grant-making organizations denied his requests for funds to research scorpion-venom molecules, Olson—in a "bold and unprecedented tactic"—started accepting donations from the families of current and for-

^{47.} See supra text accompanying note 4.

^{48.} See infra text accompanying notes 41-52.

^{49.} Larry R. Churchill, Joseph B. Fanning, & David Schenk, What Patients Teach: The Everyday Ethics of Health Care 4 (2013).

^{50.} Id. at 141.

^{51.} *Id.* at 142 (emphasis added). The concept of doubled-agency is one the authors employ to capture the dynamic of two actors—patient and physician—with separate identities, working toward a common goal, similar to the double effort in doubles tennis or a double-play in baseball. *Id.* at 115.

mer patients.⁵² In the context of relationships wrapped in vulnerabilities and reliant upon trust, the physician-researcher who actively raises money among his patients for any purpose—regardless of how "true," noble, and well-intentioned—triggers a number of ethical and moral concerns. For instance, there are knowledge and power asymmetries between physician and patient, as well as conflicts of interest that can cloud professional judgment and whittle away at a physician's ethical obligation to protect her patients' best interests. These specific concerns and the more general specter of commercialization and commodification are already pervasive in the ecology of health care in the United States.⁵³

Indeed, recent observers have become increasingly concerned about the tension between commerce and professionalism in medical care.⁵⁴ Offering a variation on the Hippocratic theme, Harvard Business School professor John H. McArthur and Harvard Medical School surgeon Francis D. Moore, writing in the late 1990s, suggested that,

The fundamental act of professional medical care is the assumption of responsibility for the patient's welfare—an unwritten . . . acknowledgement by the physician that "We will take care of you." The essential image of the professional is that of a practitioner who values the patient's welfare above his or her own and provides

Koerner, supra note 4, at 98.

^{53.} See generally Joshua E. Perry, The Ethical Costs of Commercializing the Professions: First-Person Narratives From the Legal and Medical Trenches, 13 U. PA. J.L. & Soc. Change 169, 169-201 (2010) (drawing upon interviews with physicians to explore the realities of financial pressures in the clinical environment); infra text accompanying notes 46-48.

^{54.} See John H. McArthur & Francis D. Moore, The Two Cultures and the Health Care Revolution, 277 JAMA 985 (1997) (arguing that while traditions of commercialism and professionalism both share a central role in the evolution of social institutions in the United States, "threats" exist to the "quality and scope of medical care" when "the tradition of medical professionalism is overtaken by the commercial ethic and by corporations seeking profit for investors from clinical care of the sick"); Joseph J. Fins, Commercialism in the Clinic: Finding Balance in Medical Professionalism, 16 Cambridge Q. Healthcare Ethics 425, 425 (2007) ("There is a palpable malaise in American medicine as clinical practice veers off its moorings, swept along by a new commercialism that is displacing medical professionalism and its attendant moral obligations."); William S. Andereck, Commodified Care, 16 CAMBRIDGE Q. HEALTHCARE ETHICS 398 (2007) (examining the characteristics of healthcare commodification in the context of medical care and exploring its effects on the doctor-patient relationship); Larry R. Churchill, The Hegemony of Money: Commercialism and Professionalism in American Medicine, 16 Cambridge Q. Healthcare Ethics 407 (2007) (exploring the cultural meaning attached to money and its pervasive force throughout medical research, education, and the delivery of health services); Marc A. Rodwin, Medical Commerce, Physician Entrepreneurialism, and Conflicts of Interest, 16 Cambridge Q. Health-CARE ETHICS 387 (2007) (tracing the historical development of medical commerce in the United States from the late 18th century through the early 21st century and arguing that the primary problem of commercialism in medicine today is the conflict of interest that arises in the context of physician entrepreneurship when loyalty to patients and the exercise of independent professional judgment is compromised); Jacob Needleman, A Philosopher's Reflection on Commercialism in Medicine, 16 Cambridge Q. Healthcare Ethics 433, 437 (2007) (advocating for greater self-awareness among physicians regarding those ways in which "the money factor . . . in one's own experience as a physician, now impacts the human values often assumed to define the art of medicine, understood as the work of always and in everything giving first priority to the health and well-being of the individual patient").

service even at a fiscal loss and despite physical discomfort or inconvenience. 55

While many doctors have always made a good living, the systems in which medicine is practiced have changed in recent decades and profit has, in many instances, surpassed altruism as the locus of professional concern.⁵⁶ Writing in 2007, Arnold S. Relman, a physician and former editor of *The New England Journal of Medicine* observed that "financial ambition" increasingly seems to be trumping professional ethics as physicians now labor in a dysfunctional system "incompatible with the needs of community and personal medical care and the values of medical professionalism that have traditionally shaped the behavior of our physicians."

Furthermore, it is important to note that half of all biomedical research is funded by industry and concomitantly guided by industry research priorities and design.⁵⁸ Industry, of course, is driven by profit concerns. Another significant portion of all biomedical research is funded by academic medical centers. While ostensibly driven by a non-profit mission, institutional profit, as well as institutional objectives are inevitably in the mix as research projects are supported, or not, by the researchers home academic institution. As Margaret Foster Riley argues, it becomes difficult to distinguish between industry interests, academic interests, and federal interests and the implications are "discouraging." She continues:

Some discoveries necessary to ready the foundation for future discovery are not being made. More and more dollars are diverted to research that is focused on developing products that are costlier and therefore more profitable. . . . Researchers are forced to hype their research so that they can attract private venture capital. This all leads to the question of whether all federal funds used for biomedical research are truly serving the public interest. . . . New regulatory solutions and institutions may be required. 60

As an alternative funding mechanism free of external institutional investors, i.e., industry, venture capitalist, or academia, making a research project available to the crowd suggests a potential source of revenue that might simultaneously protect the autonomy of the research scientist, while also keeping first and foremost the interests of

^{55.} See McArthur & Moore, supra note 54, at 985.

^{56.} John Lantos, RVUs Blues: How Should Docs Get Paid?, 33 HASTINGS CTR. REP. 37, 45 (2003). In the past, "doctoring was more about giving than about getting." Id. Lantos laments the new forms of physician pay that incentivize expediency and efficiency—as measured in outcomes—to the exclusion of those less measurable, vague healing skills and virtues that contribute a moral value to the physician-patient encounter. Id.

^{57.} Arnold S. Relman, *The Problem of Commercialism in Medicine*, 16 Cambridge Q. Healthcare Ethics 375, 376 (2007). Dr. Relman prescribes a renewed resistance to the tide of commercialism if physicians hope to reclaim "the moral high ground for a profession in danger of losing its moorings." *Id.*

^{58.} Margaret Foster Riley, Federal Funding and the Institutional Evolution of Federal Regulation in Biomedical Research, 5 Harv. L. & Pol'y Rev. 265, 286 (2011).

^{59.} Id.

^{60.} Id.

the future patient, as represented by the multitude of small-dollar investors. In this way, one can imagine crowdvesting of biomedical research—as long as protections are in place for the patients of physician-researchers—as a sort of democratization of the NIH, a diffusion of interests away from pure profit considerations and a re-emphasis on the types of concerns that might motivate multitudes of small-dollar crowdfunders/investors, namely the alleviation of human suffering and the sense of affiliation and connection attached to a sense of helping to finance the creation of products that are good for society.

But would such an ownership interest be permissible under existing securities laws and regulations? To that inquiry we now turn.

III. CROWDVESTING AND REGULATION

Crowdfunding is uniquely positioned to assist biomedical researchers seeking early financing necessary to convert their ideas into viable clinical trials and ultimately, successful therapeutic options for suffering patients. Much like entrepreneurs attempting to launch a business or small business owners trying to keep their enterprise solvent,⁶¹ biomedical researchers face difficult challenges in today's financial environment where traditional sources of funding such as the National Institutes of Health and National Science Foundation have increasingly smaller budgets. Depending on how avant-garde the researcher's idea might be, i.e., exploration of the potential to be found in molecules inside the stinger of the deathstalker scorpion, traditional charitable foundations, as well as private equity and capital firms, are also unlikely to be interested.⁶² Given the challenges of the current financial climate, the allure of crowdfunding's potential to provide the necessary capital to initiate cutting-edge research is significant.

Yet, despite the apparent simplicity of the crowdfunding solution for raising capital to develop and sustain the ongoing expenses of an organization, securities regulations recognize a big difference between token gifts or rewards most often featured in the campaigns initiated by artists on Kickstarter or IndieGoGo and the offer of an equity interest in the hoped-for ultimate outcome of the research. As Professor Thomas Lee Hazen has documented, "a business seeking investors through crowdfunding implicates the securities laws which provide investor protection by requiring disclosure and, in many instances, registration of securities offered to the public."63 This is, of course, in distinction to those crowdfunding efforts that seek donations without any promise of a return to the donor. Such fundraising appeals that do not offer investment interest to donors do not trigger the protections and protocols of the Securities Exchange Act of 1933 ("1933 Act") or

^{61.} Stemler, supra note 38, at 272.

^{62.} See generally, Jill E. Fisch, Can Internet Offerings Bridge the Small Business Capital Barrier?, 2 J. SMALL & EMERGING Bus. L. 57 (1998) (discussing the reality that private equity and venture capital firms provide capital to only a very small percentage of U.S. companies).

^{63.} Hazen, *supra* note 16, at 1737.

the periodic reporting requirements of the Securities Exchange Act of 1934 ("1934 Act"). 64

Passage of these federal securities laws was triggered by the stock market crash of 1929, and the legislative history reveals consumer protections were their intended effect, in addition to instituting some market stability and integrity. Provisions of the 1933 Act make it unlawful for a company to offer and sell securities without issuing detailed and audited financial statements, i.e., a prospectus, about the company. He 1934 Act mandates that publicly traded companies make additional disclosures to the Securities and Exchange Commission and to shareholders on an either quarterly or annual basis, depending on whether certain exemptions apply. In short, to advertise and sell securities pursuant to the 1933 and 1934 Acts, an organization must fully comply with a complex and expensive set of legal and regulatory requirements, fees for which can range from \$300,000 to \$500,000.68

Moreover, as Abbey Stemler has noted, "[m]ost companies interested in pursuing crowdfunding are also unable to resort to one of the registration exemptions under the Securities Act and subsequent regulations." Yet, prior to the exceptions created by the JOBS Act of 2012, proponents of crowdfunding solutions to the economic challenges facing entrepreneurs, small business owners, and, yes, biomedical researchers seeking innovative healthcare breakthroughs, had few options with regard to crowdfunding. Passed with bipartisan support, the JOBS Act rolled back a number of regulations in an effort to spur the sluggish, post-Great Recession economy. More to the point of this article, the JOBS Act included the CROWDFUND Act, which changes the landscape for those seeking to fund their economic enterprise through the power of the crowd.

^{64.} *Id.* at 1740 n.21 ("Section 2(a)(1) of the 1933 Act includes stock, notes, and investment contract within the definition of security [e.g., any note, stock, treasury stock, security future, bond, debenture, evidence of indebtedness, certificate of interest, etc.]." (citations omitted)).

^{65.} Cynthia A. Williams, *The Securities and Exchange Commission and Corporate Social Transparency*, 112 HARV. L. REV. 1197, 1221–22 (1999) ("[Felix] Frankfurter was quite explicit that the purpose of disclosure was to affect the behavior of corporate managers, bankers, and accountants.").

^{66.} Securities Act of 1933 § 5(a), 15 U.S.C. § 77e(a) (2006).

^{67.} See Hazen, supra note 16, at 1742-43.

^{68.} See William K. Sjostrom, Jr., Going Public Through An Internet Direct Public Offering: A Sensible Alternative for Small Companies? 53 Fl.A. L. Rev. 529, 554–57 (2001).

^{69.} Stemler, *supra* note 38, at 272 (discussing Regulation A and Regulation D exemptions that are recognized by the SEC).

^{70.} O'Connor, *supra* note 17, at 906 ("In an effort to do something to help the still-ailing economy, Congress passed the JOBS Act in 2012.").

^{71.} See Stemler, supra note 38, at 271 (discussing state-based legislation). Indiana is a representative state. On July 1, 2014, Indiana passed new rules for state-based crowdfunding, permitting Indiana-based investors to invest up to \$5,000 per opportunity and permitting Indiana-based entrepreneurs to raise up to \$2 million. Press Release, Office of the Ind. Sec'y of State, Secretary of State Connie Lawson Implements Crowdfunding in Indiana (July 1, 2014) (on file with author) ("Through Indiana's new crowdfunding rules, small businesses and entrepreneurs will be able to tap into the 'crowd' in search of investments to finance their business ventures."); see IC 23-19-2-2 (27) Version b.

Specifically with regard to those interested in crowdfunding, the legislation created a crowdfunding exemption permitting those seeking equity investors to raise up to \$1 million within a 12-month period without triggering the requirement to register with the SEC.⁷² Moreover, this legislation is responsible for creating reporting exceptions that permit publicly crowdfunded offerings to only make reports on an annual basis.⁷³ Companies seeking to raise money via crowdfunding are required by the JOBS Act to disclose the offering's purpose, the targeted amount to be raised, the deadline for reaching such amount, and the offering price.⁷⁴ Additionally, risks to investors also must be disclosed, along with information about the company, its officers, directors, major shareholders, and a description of the company's business, business plan, capital structure, and financial condition.⁷⁵

Investors are protected to a certain extent by the securities laws' anti-fraud protections, which cover fraud and misstatements in connection with the purchase or sale of securities.⁷⁶ In fact, the JOBS Act specifically amends relevant portions of the 1933 Act to equip investors with a remedy for misstatements and omissions made in connection with an offering under the crowdfunding exemption.⁷⁷ The enforcement efforts of the SEC are, however, limited and it is unreasonable to assume the Commission can be effective in the crowdfunding arena.⁷⁸ Moreover, given the relatively small amounts permitted to be invested under the JOBS Act's crowdfunding exceptions, as a practical matter is it unlikely that plaintiffs' firms would be sufficiently incentivized to bring suit on a contingent fee basis.⁷⁹

As securities scholar Thomas Lee Hazen has observed, "[i]t is naïve to assume that limiting offerings to small amounts per investor will deter scammers from taking advantage of investors via crowdfunding."80 Crowdfunding zealots may argue that the limited risk exposure per investor warrants less regulation and cause for concern, and yet [f]raud in small packages can be just as effective and damaging to the victims many of whom may be least able to bear the risk of even a small investment in a speculative business."81 Hazen emphasizes additional dynamics in the online crowdfunding environment:

Investors in crowdfunding offerings are likely to be strangers to the company and, as such, would have no information about the company except for what is provided by the company or the website where the securities are offered for sale. If anything, the impersonal nature of the Internet would seem to call for more,

 ^{72.} JOBS Act, Pub. L. No. 112-106, § 302, 126 Stat. 315-21 (2012).
 73. See Hazen, supra note 16, at 1743.

^{74.} JOBS Act § 302.

^{75.} *Id.*76. Securities Act of 1933 § 17, 15 U.S.C. § 77q (2006); Securities Act of 1934 § 10(b), 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5 (2011).

^{77.} JOBS Act § 302(b).

^{78.} See Hazen, supra note 16, at 1757.79. Id. at 1759.

^{80.} Id. at 1765.

^{81.} Id. at 1765-66.

rather than less, investor protection. Also, the solicitation of small investors is likely to attract more unsophisticated investors who are in need of the investor protection provisions generally found in the securities laws. It is also likely to attract investors with limited funds who cannot tolerate high investment risk, even for small amounts of money. Furthermore, if an overly permissive crowdfunding exemption were recognized, what is to prevent scammers from repeatedly going to the same investors for purportedly different investments? Even putting aside scammers who are trying to bilk the public, crowdfunding offers the potential for raising large amounts of money, warranting the mandatory disclosure that is required by the federal securities laws. 82

Hazen's concerns regarding investor protections mirror those raised by Pimple's questions in Part II as applied to concerns regarding patient protections and the special dynamics of the doctor-patient relationship. In the realm of biomedical project crowdfunding or equity crowdvesting biomedical research—especially when a physician-researcher engages her own patients—a number of additional protective and transparency measures are warranted.

Academic and independent biomedical researchers, or their representative associations such as the Institute of Medicine ("IOM"), the American Medical Association ("AMA"), and the American Association for the Advancement of Science ("AAAS") should develop an internal set of codes and restrictions, or at least advisory best practices and policies, to govern activity in this realm. With the average crowdfunding pledge under \$10083 and securities regulations already limiting the amount of intra-state equity crowdvesting investments, the potential financial harms seem relatively minimal. Internally generated protocols, such as an outright ban on physician solicitations of donations from their patients and patients' family members, a less-comprehensive prohibition merely on physician solicitation within the confines of the hospital or clinic, or even a minimal rule banning the wearing of a physician's traditional white coat when making an appeal for funds, all constitute the range of rule-making professional organizations may want to consider before triggering the attention of federal law makers and regulators.

Conclusion

In 2010, Dr. Jimmy Lin, then a medical student at Johns Hopkins University, adopted a crowdfunding model to fund Rare Genomics Institute, a start-up genetic research center.⁸⁴ Focused on raising small

^{82.} *Id.* at 1766 (citing an SEC News Release discussing the SEC's first publicized enforcement action against an effort to crowdfund the purchase of Pabst Brewing Company without first registering with the SEC) (citations omitted).

^{83.} Nick Shchetko, *There's No Refunding in Crowdfunding*, Wall St. J., Nov. 26, 2014, at B1.

^{84.} Brian Farnkoff, Comment, Crowdfunding for Biotechs: How the SEC's Proposed Rule May Undermine Capital Formation for Startups, 30 J. CONTEMP. HEALTH L. & POL'Y 131, 132

donations of money from multiple sources online, Lin's efforts demonstrate the power of bringing "disparate individuals with common concerns together through the Internet to actually fund an enterprise—in this case an organization addressing rare genetic disorders."85 Moreover, the success of Rare Genomics Institute also signals a potential solution to the dreaded "Valley of Death" problem that often makes venture capitalists particularly uncomfortable.86 Indeed, low-dollar investors captivated by the opportunity to collaborate with other low-dollar investors to aid in the research and development of life-saving therapies are apt to be "less risk averse, more attracted to the hopeful idea of the endeavor, and less concerned [than 'angel investors' or venture capitalists] with an immediate return on their investment."87 In this case, crowdfunding for biomedical research holds the potential to fill a gap created by traditional fundraising models.

As bioethicist Marleen Eijkholt has observed, crowdsourcing in the context of health care and biomedical research often includes an individualized and personal health story characterized by a devastating, incurable, or rare health condition that presents a compelling, difficultto-resist story to an online crowd.88 Eijkholt worries that presenting an online audience with sensitive health information creates future privacy, discrimination, and stigmatization risks vis-à-vis future employers, insurers, and social contexts.⁸⁹ Indeed, such detailed information existing forever in the online environment does risk heightening an individual's vulnerability.

Again, as discussed in Part II, both opportunity for entrepreneurial and positive public health outcomes must always be balanced by concerns for the welfare of individual patients. In the context of physicianresearchers, these concerns will be made particularly difficult by the existing dynamics of the complex physician-patient relationship. Physician-researchers have the potentially difficult dilemma of responsibility both to an individual patient with whom a relationship characterized by trust and vulnerability exists, as well as future patients whose suffering promises to be alleviated. And, as discussed in Part III, existing regulations both at the federal and state levels are intended to protect unso-

^{(2013),} citing E.B. Solomont, Lin's Rare Genomics: Crowdfunding A Way to A Cure, St. Louis Bus. J. (Aug. 3, 2012, 5:00 AM), http://www.bizjournals.com/stlouis/print-edition/2012/ 08/03/lins-rare-genomics-crowdfunding.html).

^{85.} Id., citing Interview with Dr. Jonathan Franca-Koh on Rare Genomics Institute's Use of a Grass Roots Approach to Raise Funds for Patients (May 22, 2013), http://www .youtube.com/watch?v=2fmY1EDT2P0.

^{86.} See Evan Mills & Jonathan Livingston, Traversing the Valley of Death, FORBES (Nov. 17, 2005, 4:00 PM), http://www.forbes.com/2005/11/17/utilities-emerging-tech-cz_1117 energy_programs.html. The term "Valley of Death" refers to the funding gap encountered by early stage companies who get caught between initial rounds of investment from friends and family and the larger, more sustainable follow-up rounds of funding from venture capitalists.

^{87.} Farnkoff, supra note 84, at 158–59.

^{88.} Marleen Eijkholt, Health Care and Crowdsourcing: A CrowdCry for Help, BIOETHICS Today (July 1, 2014), www.amc.edu/BioethicsBlog/post.cfm/health-care-and-crowdsourc ing-a-crowdcry-for-help.

^{89.} Id.

phisticated investors. Con artists and securities fraudsters have found fertile ground in the Internet's various social media outlets. Adequate disclosures and other regulatory protections are therefore justified by the inevitable specter of fraud.

Of course, it must be highlighted that the case of Jim Olson, discussed in the Introduction, suggests none of the adverse consequences to patients and their families explored in Part II's ethical analysis or the chicanery that disclosures are intended to thwart referenced in Part III's discussion of the governing legal and regulatory regime. Indeed, Dr. Olson's use of crowdfunding appears to be nothing more than a variation on the theme of charitable fundraising through the efficiencies and mechanisms that exist in 2015. Yet, the fact remains that Dr. Olson's crowdfunded research is creating an intellectual property portfolio with both long-term expenses and potentially lucrative returns. Moreover, Dr. Olson is probably best seen as a pioneer in his explicit use of the crowd to fundraise. Others will surely follow, and tapping larger amounts of crowdfunded capital by offering an equity interest is sure to be an attractive funding vehicle. As Sean O'Connor has observed, based on his ten years of experience as counsel to start-up companies in private practice and through the Entrepreneurial Law Clinic at the University of Washington Law School, patents, for example, can take a year or more to prosecute, with attendant costs in the tens of thousands of dollars.⁹² Cash-strapped researchers are unlikely to have the extra budget required to prosecute the patent, and crowdvesting suggests a potentially viable way to raise these necessary funds.

Ultimately, the power of mobilizing large numbers of small-dollar funders to assist in the advancement of medicine offers an important opportunity for the masses to engage with science and take a more active role in the creation of next generation therapies. Moreover, this democratized approach to biomedical research suggests a less-fettered agenda in which institutional stakeholders in industry or academia do not have to be satisfied. The enthusiasm I am suggesting, however, is tempered by the real concerns around deception and manipulation, first of actual patients (and especially if the physician-researcher is attempting to solicit funds from her current patients) and second of compassionate investors simply seeking to do good (while doing well) with their investment resources. Assuming these concerns can be addressed, the future opportunities at both the federal and state level

^{90.} See Hazen, supra note 16, at 1767 (citing to John Rothchild, Protecting the Digital Consumer: The Limits of Cyberspace Utopianism, 74 Ind. L.J. 893, 898 (1999)).

^{91.} Andrew A. Schwartz, *Crowdfunding Securities*, 88 Notre Dame L. Rev. 1457, 1489 (2013).

^{92.} O'Connor, *supra* note 17, at 898. As O'Connor documents, patents and other IP rights are critically important to the long-term success of a start-up, and if venture capital, angels, friends and family, or personal resources are not available, alternative avenues may be required. "Given the interest in funding innovation evinced by contributors to Kickstarter, IndieGoGo, and similar sites, crowdfunding seems to be a natural fit." *Id.* at 900.

for the crowd to engage, as micro-investors, in the financial support of biomedical research are opportunities that are worthy of continuing and careful promulgation.