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Scouting For Approval: Lessons on Medical Device Regulation in an Era of Crowdfunding from Scanadu's "Scout"

Colleen Smith

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COLLEEN SMITH*

I. INTRODUCTION

In November of 2012, Scanadu, an up-and-coming medical device company based in Mountain View, California, introduced the world to the Scout.[1] The Scout is a "hockey puck-shaped device" that Scanadu says is capable of measuring a multitude of vital signs, including temperature, heart rate, respiratory rate, and oxygen levels in the blood.[2] To use the Scout, a consumer simply places the Scout to her temple for ten seconds.[3] The Scout collects and sends the measurements to the consumer's cell phone via Bluetooth LE, and the information is analyzed and tracked through a companion smartphone application.[4] Scanadu is also developing two accessories for the device: the ScanaFlu, an influenza tester, and the ScanaFlo, a urinalysis device.[5]

In May of 2013, to fund the Scout's commercial development, Scanadu launched a crowdfunding campaign on Indiegogo,[6] one of the world's most popular crowdfunding websites.[7] Crowdfunding, an increasingly popular method of raising capital, is the process of raising money for a project, usually via the Internet, by obtaining many small contributions from a large number of people.[8] In just two hours, Scanadu passed its goal

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1 Press Release: *Scanadu Aims to Empower Patients with DIY Vital Signs Device*, SCANADU (Nov. 29, 2012), http://www.scanadu.com/pr/scanadu-aims-to-empower-patients-with-diy-vital-signs-device/.

2 Matt Brian, *Scanadu Scout 'Medical Tricorder' for Smartphones Breaks Crowdfunding Record*, VERGE (July 23, 2013), http://www.theverge.com/2013/7/23/4548336/scanadu-scout-health-tracking-smartphone-accessory-record.

3 Mike Flacy, *Scanadu Scout Makes Star Trek's Medical Tricorder a Reality*, DIGITAL TRENDS (May 23, 2013), http://www.digitaltrends.com/gadgets/scanadu-scout-makes-star-treks-medical-tricorder-a-reality/#ixzz2l4Fy1hZ0.

4 *Id.*

5 Jonah Comstock, *Scanadu to Crowdfund Its Tricorder Device Pre-FDA Clearance*, MOBIHEALTHNEWS (May 22, 2013), http://mobihealthnews.com/22516/scanadu-to-crowdfund-its-tricorder-device-pre-fda-clearance/.

6 Brian, *supra* note 2.

7 Chance Barnett, *Donation-Based Crowdfunding Sites: Kickstarter vs. Indiegogo*, FORBES (Sept. 9, 2013), http://www.forbes.com/sites/chancebarnett/2013/09/09/donation-based-crowdfunding-sites-kickstarter-vs-indiegogo/.

8 Paul Belleflamme, Thomas Lambert & Armin Schwienbacher, *Crowdfunding: Tapping the Right Crowd*, 29 J. BUS. VENTURING 585, 586 (2014).

of raising $100,000.[9] Over the course of its thirty-day campaign, Scanadu raised—a then Indiegogo record—$1.66 million from 8,500 contributors.[10]

Scanadu used the most prevalent crowdfunding model for its campaign: the pre-purchase model.[11] The pre-purchase model enables contributors to "pre-order" whatever product the crowdfunder is trying develop for commercial sale in exchange for a financial contribution.[12] In this case, contributors to Scanadu's campaign "bought" the prototype of the Scout.[13] Scanadu's campaign site advertised that it expected to ship the prototype of the Scout to contributors by March of 2014[14] and hoped to make the Scout available to the general public in early 2015.[15] There is, however, one major hurdle that stands in Scanadu's way on its quest to bring the Scout to market: FDA approval.

Scanadu has acknowledged that FDA will need to approve the Scout before it is made available to the public.[16] A company seeking to sell a medical device in the United States has to obtain FDA approval before it can sell, distribute, or even market the device.[17] To gain approval, Scanadu will have to conduct clinical trials, and those trials will have to demonstrate the efficacy of the device.[18] Scanadu tried to subvert this requirement and, in violation of FDA regulations, made the prototype of the Scout available to consumers prior to FDA approval by stating in its crowdfunding campaign materials that the prototype of the Scout "is not a medical device and makes no medical claims."[19] Instead, Scanadu pronounced that the Scout was a "research tool" that "can be used to collect data that will be submitted in a marketing application to the regulatory authorities."[20] Scanadu used its crowdfunding campaign not only to raise money, but also to acquire individuals willing to participate in its clinical trials; Scanadu gave all campaign contributors who will be receiving the Scout the option to participate in its trials.[21]

It should be no surprise that Scanadu turned to crowdfunding as a primary source of capital. Hundreds of other companies and individual entrepreneurs have done the same thing over the past few years, many with great success.[22] The business world is utilizing crowdfunding more and more partly because it offers advantages beyond

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[9] Brian, *supra* note 2.

[10] *Id.*

[11] Ethan Mollick, *The Dynamics of Crowdfunding: An Exploratory Study*, 29 J. BUS. VENTURING 1, 3 (2014).

[12] Joachim Hemer, *A Snapshot on Crowdfunding* 2 (Fraunhofer Inst. for Sys. and Innovation Research ISI, Working Paper No. R2, 2011).

[13] *Scanadu Scout*, INDIEGOGO, https://www.indiegogo.com/projects/scanadu-scout (last visited Feb. 18, 2015).

[14] *Id.*

[15] Brian, *supra* note 2.

[16] *Scanadu Scout*, *supra* note 13 (explaining in its crowdfunding campaign materials that Scanadu will "still have to file with the FDA").

[17] *See infra* Part III.A.

[18] *See infra* Part III.B.

[19] *Scanadu Scout*, *supra* note 13 ("The exploratory version of the Scanadu Scout™ is not a medical device and makes no medical claims. It is still in development and can only be used as part of an investigation. As an investigational product, it can be used to collect certain data and must be used in accordance with the study's protocol.").

[20] *Scanadu Scout, the First Medical Tricorder*, GOBACKERS, http://www.gobackers.com/projects/scanadu-scout-the-first-medical-tricorder/ (last visited Feb. 18, 2015).

[21] *Id.*

[22] *See, e.g.*, MASSOLUTION, 2013CF: THE CROWDFUNDING INDUSTRY REPORT (2013), *available at* http://www.crowdsourcing.org/editorial/2013cf-the-crowdfunding-industry-report/25107.

simply providing a cash-strapped company with the means to get off the ground.[23] On average, it costs medical device companies tens of millions of dollars to run clinical trials and pay for an application for FDA approval.[24] Accordingly, the federal regulation of medical devices functions as an almost insurmountable barrier to market entry; without a means to enter the U.S. market, innovation is quashed and companies are driven to countries with easier market entry.[25] Crowdfunding can be invaluable to a small medical device company that is struggling to attract investors, not only because it provides access to much-needed start-up capital, but also because it offers many other benefits, including consumer feedback in the early stages of development, which this Article will later explain.[26]

Because Internet crowdfunding is a relatively new method of raising capital, there is limited academic literature on the subject. The majority of legal scholarship on crowdfunding focuses on the equity model of crowdfunding and its interaction with federal securities laws.[27] As its name implies, using the equity model, "crowdfunders invest money in order to receive ownership interests in a company."[28] In addition, past authors have scrutinized medical device regulations and proposed improvements for their flaws.[29] However, this Article's focus on the interaction of these two subject areas—medical device regulation and crowdfunding—raises issues novel to the world of legal literature.

This Article will argue that medical device companies should be able to utilize crowdfunding to raise the necessary capital to develop a product. However, because of the risks medical devices pose, any solution that allows medical device companies to employ crowdfunding should ensure the continuing commitment to consumer safety that is at the core of FDA regulation. This Article uses the Scanadu Scout as an example and a staring point for evaluating the use of crowdfunding in the medical device industry. This Article explains how and why Scanadu broke the law when it moved the Scout, an "adulterated or misbranded" medical device, through interstate commerce in violation

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[23] Jenna Wortham, *Start-Ups Look to the Crowd*, N.Y. TIMES (Apr. 29, 2012), http://www.nytimes.com/2012/04/30/technology/kickstarter-sets-off-financing-rush-for-a-watch-not-yet-made.html?.

[24] JOSH MAKOWER ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION: A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES 7 (2010), *available at* http://eucomed.org/uploads/Press%20Releases/FDA%20impact%20on%20U.S.%20Medical%20Technology%20Innovation.pdf.

[25] *See* Christina Farr, *Entrepreneurs Say the FDA Is Killing Medical Innovation*, VENTUREBEAT (Apr. 30, 2013), http://venturebeat.com/2013/04/30/stifled-by-regulation-entrepreneurs-take-life-saving-devices-overseas/; *see also* Andrew Pollack, *Medical Treatment, Out of Reach*, N.Y. TIMES (Feb. 9, 2011), http://www.nytimes.com/2011/02/10/business/10device.html?pagewanted=all (explaining that many companies are choosing to sell their products in countries such as Mexico, Canada, Brazil, India, China, and all over Europe, but not the United States, because these countries have less stringent, and thus less expensive, medical device regulations); Henry I. Miller, *U.S. Medical Device Industry in Critical Condition*, FORBES (July 24, 2013), http://www.forbes.com/sites/henrymiller/2013/07/24/u-s-medical-device-industry-in-critical-condition/ ("[M]any device firms are shutting down or moving abroad to take advantage of the more favorable tax and regulatory climate in Europe.").

[26] *See infra* Part II.A.

[27] *See, e.g.*, Stuart R. Cohn, *The New Crowdfunding Registration Exemption: Good Idea, Bad Execution*, 64 FLA. L. REV. 1433 (2012); Joan MacLeod Heminway & Shelden Ryan Hoffman, *Proceed at Your Peril: Crowdfunding and the Securities Act of 1933*, 78 TENN. L. REV. 879 (2011); David Mashburn, Comment, *The Anti-Crowd Pleaser: Fixing the Crowdfund Act's Hidden Risks and Inadequate Remedies*, 63 EMORY L.J. 127 (2013); John S. Wroldsen, *The Social Network and the Crowdfund Act: Zuckerberg, Saverin, and Venture Capitalists' Dilution of the Crowd*, 15 VAND. J. ENT. & TECH. L. 583, 589 (2013).

[28] Wroldsen, *supra* note 27, at 589.

[29] *See, e.g.*, Michael VanBuren, Note, *Closing the Loopholes in the Regulation of Medical Devices: The Need for Congress to Reevaluate Medical Device Regulation*, 17 HEALTH MATRIX 441 (2007).

of 21 U.S.C. § 331(a). This Note goes on to explain what this means for other medical device companies looking to copy Scanadu's strategy.

Part II of this Article begins with an explanation of crowdfunding, its origins, and a description of the four different crowdfunding models. Part II also describes the many benefits of crowdfunding and why the medical device industry would profit from them.

Part III provides some historical context for FDA's regulation of medical devices and examines the modern structure of the regulations, including how medical devices are classified and the different hurdles companies face when trying to bring a medical device to market.

Part IV first explains how, by giving all campaign contributors the option of participating in the Scout's clinical trials, Scanadu created two different groups of consumers—the non-participants and the participants. Part IV.A analyzes 21 U.S.C. § 331(a) and explains how and why Scanadu's actions, in regard to the non-participants, were a violation of this code section. Using Scanadu's strategy as a starting point, this Part looks at how a medical device company can use crowdfunding legally. Specifically, this Part explains that if a device company wants to use the pre-purchase model, consumers should be able to "pre-order" a device prior to FDA approval, but should not be able to receive the product until after the device has received FDA approval. This section looks at Biosense, a company that is using this permissible strategy.

Part IV.B analyzes Scanadu's actions in regard to the group of contributors who opted to participate in the Scout's clinical trials. This Part argues FDA should not give campaign contributors the option to participate in clinical trials as a "perk" for backing the product, and the investors and test subjects should remain separate. This Part reasons that permitting the overlap of these two groups creates a moral hazard that may ultimately affect the safety and efficacy of the device.

Section V argues that FDA should adopt and enforce guidelines for crowdfunding that reflect the principles outlined in this Article. Additionally, this Part argues that FDA should promulgate regulations that prevent crowdfunding websites from allowing medical devices to be crowdfunded using a pre-purchase model without following FDA guidelines. This Part explains that FDA has limited resources to police medical device companies while crowdfunding sites have gatekeepers that review every application to execute a crowdfunding campaign. By adopting this policy, FDA will gain an ally in its effort to protect consumers.

II. AN INTRODUCTION TO CROWDFUNDING

Crowdfunding is a new and exciting way for undercapitalized companies and individuals to fund their ideas. This Part provides some background on crowdfunding, explains the four prevalent models of crowdfunding, and explains why, due to the recent drop in investment in medical device development, crowdfunding is a particularly attractive option for device companies.

Crowdfunding is the practice of asking for money to fund a specific goal, generally through a website dedicated to crowdfunding, from anyone who will listen.[30] Individuals and businesses alike use crowdfunding to raise money for a vast array of things: to produce a movie, develop a new gadget, or support a charity.[31] Although crowdfunding is not an entirely new concept,[32] the advent of websites dedicated to crowdfunding has given

[30] Belleflamme et al., *supra* note 8, at 586.

[31] Wortham, *supra* note 23.

[32] For more information on the history of crowdfunding, see *The History of Crowdfunding*, FUNDABLE, http://www.fundable.com/crowdfunding101/history-of-crowdfunding (last visited Nov. 9, 2013).

life to this alternative means of finance.[33] An ever-expanding group of entrepreneurs and charities are utilizing crowdfunding in a vast number of sectors.[34] Crowdfunders worldwide raised $2.7 billion dollars in 2012 through more than 1.1 million campaigns; this was an 81% increase from 2011.[35] This fast-growing trend promises to change how our society apportions investment capital.[36]

An individual or company seeking to utilize crowdfunding ("crowdfunder") must first have a project or product for which to raise money.[37] The crowdfunder then selects one of the many websites dedicated to crowdfunding,[38] also called "CF platforms," through which to hold their crowdfunding campaign.[39] CF platforms allow crowdfunders to develop a profile page containing information about the project and its creators, photos, videos, dates of the campaign, fundraising goal, and the crowdfunding model, including any rewards for contributing.[40] Many CF platforms have an "all-or-nothing" policy meaning if a campaigner does not reach its stated fundraising goal it does not receive any of the contributed funds.[41] If the campaigner reaches its goal, the CF platform usually keeps a percentage of the money raised as a fee.[42] When the campaign ends, the funds are transferred directly from contributors' credit cards to the crowdfunder's account.[43] Finally, the crowdfunder is obligated to fulfill the rewards, if any, it promised to contributors.[44]

A. *Why Crowdfund?*

Crowdfunding offers benefits that many other forms of financing do not. It is particularly attractive for small and/or new companies that typically struggle to raise

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[33] Daniela Castrataro, *A Social History of Crowdfunding*, SOC. MEDIA WK. (Dec. 12, 2011), http://socialmediaweek.org/blog/2011/12/a-social-history-of-crowdfunding/#.Un6NNhZ5nzJ.

[34] Ajay K. Agrawal, Christian Catalini & Avi Goldfarb, *The Geography of Crowdfunding* 4 (2011) (Nat'l Bureau of Econ. Research, Working Paper No. 16820, 2011) (citing KEVIN LAWTON & DAN MAROM, THE CROWDFUNDING REVOLUTION: SOCIAL NETWORKING MEETS VENTURE FINANCING (2010)), *available at* http://www.nber.org/papers/w16820.pdf.

[35] MASSOLUTION, *supra* note 22.

[36] *See* Castrataro, *supra* note 33; *see also* KEVIN LAWTON & DAN MAROM, THE CROWDFUNDING REVOLUTION: SOCIAL NETWORKING MEETS VENTURE FINANCING (2010).

[37] *Creator Handbook: Getting Started*, KICKSTARTER, https://www.kickstarter.com/help/handbook/getting_started (last visited Jan. 22, 2014).

[38] Individuals or companies can also crowdfund on their own, using their own website or other platform to garner contributions from a crowd of people. LAWTON & MAROM, *supra* note 36.

[39] *See* Hemer, *supra* note 12, at 15.

[40] *See* Tanya Prive, *What Is Crowdfunding and How Does It Benefit the Economy?*, FORBES (Nov. 27, 2012) http://www.forbes.com/sites/tanyaprive/2012/11/27/what-is-crowdfunding-and-how-does-it-benefit-the-economy/; *see also Creator Handbook: Funding*, KICKSTARTER, https://www.kickstarter.com/help/handbook/funding (last visited Feb. 18, 2015).

[41] *Kickstarter Basics: Kickstarter 101*, KICKSTARTER, http://www.kickstarter.com/help/faq/kickstarter+basics?ref=faq_nav#Kick (last visited Jan. 22, 2014).

[42] For example, Kickstarter's fee is five percent of all money raised in crowdfunding campaigns on its site, while Indiegogo takes four percent of all money raised. *Id.*; *Fees and Pricing*, INDIEGOGO, http://support.indiegogo.com/entries/20492953-fees-pricing (last visited Feb. 18, 2015).

[43] For example, Indiegogo transfers funds into the fundraiser's PayPal account. *Indiegogo Playbook: After Your Campaign*, INDIEGOGO, https://go.indiegogo.com/playbook/life-cycle-phase/finishing-strong (last visited Feb. 18, 2015). Kickstarter transfers money into the fundraiser's Amazon Payments account. *Creator Questions: Getting Started*, KICKSTARTER, https://www.kickstarter.com/help/faq/creator+questions (last visited Feb. 18, 2015).

[44] *Indiegogo Playbook: After Your Campaign*, *supra* note 43; *Creator Handbook: Rewards*, KICKSTARTER, https://www.kickstarter.com/help/handbook/rewards (last visited Feb. 18, 2015).

capital through traditional means.[45] Crowdfunding is quickly becoming a main source of "seed financing" for small entrepreneurs because the process is simple, easy to understand, and financially safe.[46] CF platforms provide an additional advantage for financially inexperienced entrepreneurs.[47] These sites, such as Kickstarter or Indiegogo, give crowdfunders a platform to sell themselves and their project and provide access to potential investors.[48] Many CF platforms offer other valuable fundraising services to help crowdfunders run successful campaigns. For example, some sites "give advice, organize public relations, [and] make arrangements with micro-payment providers."[49]

For example, a crowdfunding campaign acts as a good barometer of public interest.[50] If there is no market for a product, the campaign will get a minimal number of backers.[51] Because this measurement of interest typically comes early in the development of a project, a campaign that receives little attention or support will "fail quickly," saving the developers time and capital.[52]

A crowdfunding campaign can also perform a marketing function by creating interest in the project early in its development.[53] A campaign that is particularly successful or unique may also generate media attention.[54] All of these aspects of a successful crowdfunding campaign signal to venture capitalists a startup's market potential.[55] Accordingly, crowdfunding can be a means of obtaining larger amounts of funding later on through more traditional avenues.[56] According to one report, twenty-eight percent of successful crowdfunders received investments from traditional venture capitalist or angel investors within three months of completing their campaign.[57] GoldieBlox, a toy that promotes an interest in engineering in girls age four to nine, is a prime example.[58] The makers of GoldieBlox signed an agreement with Toys "R" Us after it raised $280,000 and pre-sold 20,000 toys via its successful Kickstarter campaign.[59] Similarly, just a few

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[45] C. Steven Bradford, *Crowdfunding and the Federal Securities Laws*, 2012 COLUM. BUS. L. REV. 1, 27 (2012); Belleflamme et al., *supra* note 8, at 586 ("Many entrepreneurial ventures remain unfunded, partly because of a lack of sufficient value that can be pledged to financial investors and partly because of unsuccessful attempts to convince investors." (citations omitted)).

[46] Hemer, *supra* note 12, at 2 ("CF is on the verge of also becoming a substitute seed financing source for entrepreneurial ventures that have difficulties raising capital from traditional sources like bank loans, angel capital, VC, state promotion and others because they appear too exotic, too innovative to be understood, too complex, too crazy, too risky or which are, simply, poorly presented.").

[47] *See id.* at 10.

[48] *Id.*

[49] *Id.*

[50] Mollick, *supra* note 11, at 3.

[51] *Id.*

[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] Joel A.C. Baum & Brian S. Silverman, *Picking Winners or Building Them? Alliance, Intellectual, and Human Capital as Selection Criteria in Venture Financing and Performance of Biotechnology Startups*, 19 J. BUS. VENTURING 411, 415 (2004).

[56] Mollick, *supra* note 11, at 3.

[57] Cheryl Conner, *New Report: The ROI of Crowdfunding*, FORBES (Jan. 21, 2014), http://www.forbes.com/sites/cherylsnappconner/2014/01/21/new-report-the-roi-of-crowdfunding/.

[58] Alexandros Stefanakis, *From Crowd to Retail*, LAUNCHT (July 17, 2013), http://www.launcht.com/blog/2013/07/17/from-crowd-to-retail/.

[59] *Id.*

months after its wildly successful crowdfunding campaign, Scanadu accrued $10.5 million in Series A[60] financing.[61]

Contributors to crowdfunding campaigns do not just contribute capital to companies; they can also reduce the cost of product development by giving feedback on design improvements and consumer preferences.[62] In this way, the crowd creates value for the crowdfunder by providing free labor.[63] Crowds are also an efficient way to problem-solve; the "collective intelligence" of crowds creates better solutions to problems than individuals on their own.[64]

Finally, crowdfunding allows entrepreneurs to obtain financing while allowing them to retain ownership of their entire company.[65] By retaining complete ownership, entrepreneurs have control over the entire product development process and can see their vision come to fruition.[66] They can accept and incorporate feedback from contributors, but they are not required to compromise on anything.[67] Crowdfunding is also advantageous because it allows entrepreneurs to choose the crowdfunding model that suits their product best.

B. *Four Models of Crowdfunding*

Crowdfunding can take one of four forms: the donation model, the lending model, the equity model, or the reward/pre-purchase model.[68] Different crowdfunding platforms allow different models, each with its own benefits and disadvantages.

The first model, the donation model, is based on the concept of philanthropy.[69] Someone who contributes to a campaign based on the donation model expects nothing in return.[70]

An entrepreneur using the second model, the lending model, to raise capital asks contributors to give the campaign a temporary loan.[71] At the very least, contributors expect the entrepreneur to return the money that was loaned.[72] Some CF platforms using the lending model also give contributors a rate of return on their investment.[73]

Campaigns based on the third model, the equity model, treat contributors like investors and give "equity stakes or similar consideration" in exchange for a contribution.[74] This model was not permitted in the United States until the Jumpstart Our Business Startups

[60] "Series A Financing" is "[t]he first round of financing undergone for a new business venture after seed capital. Generally, this is the first time that company ownership is offered to external investors." *Series A Financing*, INVESTOPEDIA, http://www.investopedia.com/terms/s/seriesa.asp (last visited Jan. 28, 2014).

[61] Eliza Brooke, *Scanadu Closes $10.5M Series A Round, Gearing Up to Send Its Medical Tricorder Through Clinical Testing*, TECHCRUNCH (Nov. 12, 2014), http://techcrunch.com/2013/11/12/scanadu-closes-10-5m-series-a-round-gearing-up-to-send-its-medical-tricorder-through-clinical-testing/.

[62] Armin Schwienbacher & Benjamin Larralde, *Crowdfunding of Small Entrepreneurial Ventures*, *in* THE OXFORD HANDBOOK OF ENTREPRENEURIAL FINANCE 372–74, 379 (Douglas Cumming ed., 2012).

[63] *See* Hemer, *supra* note 12, at 5.

[64] *Id.* at 5–6.

[65] THOMAS ELLIOT YOUNG, THE EVERYTHING GUIDE TO CROWDFUNDING: LEARN HOW TO USE SOCIAL MEDIA FOR SMALL-BUSINESS FUNDING 17 (2013).

[66] *See id.*

[67] *See id.*

[68] Bradford, *supra* note 45, at 14–15; Mollick, *supra* note 11, at 3.

[69] Mollick, *supra* note 11, at 3.

[70] *Id.*

[71] *Id.*

[72] Bradford, *supra* note 45, at 20–23.

[73] *Id.*

[74] Mollick, *supra* note 11, at 3.

Act, passed in April of 2012.[75] The equity model is heavily regulated by the SEC and is rarely used, both inside and outside of the United States.[76]

Entrepreneurs, who have based their campaign on the forth model, the reward or pre-purchase model, give contributors a reward for supporting their projects.[77] The reward can take many forms including "naming a character after a backer" or getting to meet the project creators.[78] Most often, crowdfunders give contributors the actual product that the campaign is funding.[79] Crowdfunders regard these individuals as "early customers" and often give them "access to the products . . . at an earlier date, [a] better price, or . . . some other special benefit."[80] In essence, this model creates a means of pre-selling a product[81] and, as of 2013, was the most prevalent model.[82]

C. *Restrictions on the Pre-Purchase Crowdfunding Model*

Most crowdfunding websites have restrictions on what crowdfunders are allowed to "pre-sell" in their crowdfunding campaigns.[83] Many of these restrictions prevent campaigns from selling illegal or dangerous items. For example, Indiegogo, the site that Scanadu used to fund the development of the Scout, states in its terms of service that crowdfunders cannot offer, among other things, "[f]irearms or weapons"; "[p]rescription or illegal drugs"; and "[p]ornography or sexually explicit materials."[84]

Some crowdfunding platforms have additional restrictions based not on illegality, but on consumer protection or the individual preferences and goals of the particular site. For example, Kickstarter, a crowdfunding website that funds only "projects,"[85] lists a host of items that cannot be funded using its site, including drug paraphernalia, "genetically modified organisms," and "[a]ny item claiming to cure, treat, or prevent an illness or condition (whether via a device, app, book, nutritional supplement, or other means)."[86] Because of Kickstarter's restrictions, Scanadu could not have used Kickstarter for its crowdfunding campaign.

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[75] *Id.* For more information about the equity model and its interaction with the JOBS Act see sources cited *supra* note 27.

[76] MASSOLUTION, *supra* note 22 (explaining $116 million was raised in 2012 using equity-based crowdfunding, this is just 0.4% of all crowdfunded money raised worldwide).

[77] Mollick, *supra* note 11, at 3.

[78] Bradford, *supra* note 45, at 16–17.

[79] *Id.*

[80] Mollick, *supra* note 11, at 3.

[81] *See id.*; *see also* Hemer, *supra* note 12, at 14 ("[C]rowdfunding is basically an advance order of a product and represents a purchasing act.").

[82] Mollick, *supra* note 11, at 3; *see also* Belleflamme et al., *supra* note 8, at 8 n.4 (finding, in a sample of crowdfunding campaigns, that "43% are based on either profit sharing or pre-ordering, 15% are equity based, 14% are lending based, and the remainder are donation based").

[83] These crowdfunding sites were used, in part, because they were included on Forbes's top six crowdfunding websites. *See* Kate Taylor, *6 Top Crowdfunding Websites: Which One Is Right for Your Project?*, FORBES (Aug. 6, 2013), http://www.forbes.com/sites/katetaylor/2013/08/06/6-top-crowdfunding-websites-which-one-is-right-for-your-project/ (listing Kickstarter, Indiegogo, RocketHub, FundRazr, GoGetFunding, and StartSomeGood as the top six crowdfunding websites).

[84] *Prohibited Perks*, INDIEGOGO, https://support.indiegogo.com/hc/en-us/articles/204255166 (last visited Feb. 18, 2015).

[85] *Our Rules*, KICKSTARTER, https://www.kickstarter.com/rules (last visited Feb. 18, 2015).

[86] *Prohibited Items*, KICKSTARTER, https://www.kickstarter.com/rules/prohibited (last visited Feb. 18, 2015). When Kickstarter's "Prohibited Items" list was first surveyed during the course of writing this paper, back in February of 2014, this list included "medical, health, safety, and personal care products." *See* Leo Sun, *3 Amazing Medical Technologies Developed on Kickstarter and Indiegogo*, MOTLEY FOOL (Feb. 14, 2014),

Kickstarter co-founder Yancey Strickler explained that the company utilizes such stringent limitations on what projects can be funded through its site because of the corrupting power of advertising.[87] Products typically are not fully developed at the crowdfunding stage, and Kickstarter wants to discourage crowdfunders from overselling, or undertaking too much, and trying to figure out how to fulfill the promises later.[88]

Kickstarter, like most crowdfunding sites, has an "all-or-nothing" policy.[89] Kickstarter has sound reasons for this policy: it motivates people to spread the word about a project they are excited about, and it creates less risk for everyone because a crowdfunder will not be expected to complete an expensive project if they only raise a fraction of the needed funds.[90] However, this policy also creates perverse incentives: crowdfunders may exaggerate the quality or capabilities of their project knowing they will not receive any money if they do not meet their goal.[91]

Strickler explained that the consequences of over-advertising are amplified when it comes to medical devices and products.[92] When Kickstarter was created in 2009, it allowed medical products to be funded through its site.[93] Kickstarter only banned medical devices and products after continually receiving project applications making deceitful or hyperbolic medical claims.[94] Knowing FDA regulates medical products, Kickstarter now refuses to host crowdfunding campaigns selling them.[95] Not all crowdfunding sites share Strickler's sentiments. In response to Kickerstarter's rebuff of medical products, several healthcare-focused crowdfunding sites launched, including Medstartr, Health Tech Hatch, and WeFundr.[96] These healthcare-specific sites could be advantageous to the medical device industry, which has recently experienced a downturn in investment.

D. *Alternative Sources of Funding for Medical Device Companies Are Needed*

Experts estimate that investment in the medical device industry is down significantly: 2012 saw a thirteen percent decrease in the amount of money spent in the industry from 2011 and a fifteen percent decrease in the number of deals made.[97] Even more staggering, in 2012 the number of "first-time financings" in the medical device industry dropped to 1995 levels.[98] Part of what is causing this drop in investment is that it is taking longer

http://www.fool.com/investing/general/2014/02/14/3-amazing-medical-technologies-developed-on-kickst.aspx#lastVisibleParagraph.

[87] Olivia Solon, *Kickstarter's Yancey Strickler: The Culture of Advertising Has Been a Corrupting One*, WIRED (Oct. 29, 2013), http://www.wired.co.uk/news/archive/2013-10/18/yancey-strickler-kickstarter.

[88] *Id.*

[89] *See Kickstarter Basics: Kickstarter 101*, *supra* note 41.

[90] *Id.* ("If you need $5,000, it's tough having $1,000 and a bunch of people expecting you to complete a $5,000 project.").

[91] *See id.*; *see also* Solon, *supra* note 87.

[92] Solon, *supra* note 87.

[93] Brian Dolan, *Medstartr to Launch After Kickstarter Rejects (Some) Health Projects*, MOBIHEALTHNEWS (July 10, 2012), http://mobihealthnews.com/17841/medstartr-to-launch-after-kickstarter-rejects-some-health-projects/.

[94] Solon, *supra* note 87.

[95] *Id.*

[96] *See* Dolan, *supra* note 93; *see also* Sophie Park, *LUMOback: A Crowdfunding Success*, HEALTH 2.0 (July 6, 2012), http://www.health2con.com/news/2012/07/06/13885/.

[97] Press Release: *Annual Venture Investment Dollars Declined for First Time in Three Years, According to the MoneyTree Report*, PRICEWATERHOUSECOOPERS LLP (Jan. 18, 2013), http://www.pwc.com/us/en/press-releases/2013/annual-venture-investment-dollars.jhtml.

[98] *Id.*

than ever to guide a medical device through the applicable regulations and bring it to market.[99] Michael Carusi, a venture capitalist specializing in biopharmaceuticals and medical devices, says this is having a detrimental effect on the U.S. medical device market. "[T]he sad reality," Carusi said, "is that medical device innovation is being driven out of the U.S. because of too much regulation."[100] Investment in medical device development is also being discouraged in other ways. For example, the Affordable Care Act contains a provision that imposes a 2.3% excise tax on the revenues made from medical device sales starting on December 31, 2012.[101]

Part of FDA's mission is promoting innovation in the medical device industry. However, a more fundamental goal of FDA's is protecting consumer safety. This Note will now discuss the regulations that advance this objective.

III. MEDICAL DEVICES AND FDA

To fully understand the regulation of medical devices in the United States, it is helpful to have some background on the roots of FDA and the historical context that gave rise to the modern system of medical device regulation. This Part explains the current regulatory scheme and the different paths companies can take to gain FDA approval of their medical devices.

A. *The Medical Device Amendments of 1976*

The modern system of medical device regulation is largely a result of the Medical Device Amendments of 1976 (MDAs) to the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA).[102] Before the MDAs, pharmaceutical companies only had to submit drugs, but not medical devices, for FDA approval prior to putting them on the market.[103] The MDAs extended this pre-market approval requirement to medical devices.[104]

The MDAs were a reaction to the Dalkon Shield disaster.[105] The Dalkon Shield was an intrauterine birth control device marketed in the early 1970s.[106] Because FDA did not have the authority to regulate the Dalkon Shield—as it was a medical device—its producer never had to demonstrate that it was safe and effective.[107] Women who used the Dalkon Shield suffered from "miscarriages, pelvic inflammatory disease, and unplanned pregnancies."[108] FDA estimates that the Dalkon Shield affected 200,000 women and killed at least seventeen.[109] The public outcry after this tragedy provoked Congress to strengthen the regulation of medical devices and ultimately pass the MDAs.[110]

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[99] Farr, *supra* note 25.

[100] *Id.*

[101] I.R.C. § 4191 (2012); *Medical Device Excise Tax: Frequently Asked Questions*, INTERNAL REVENUE SERVICE (Feb. 3, 2014), http://www.irs.gov/uac/Medical-Device-Excise-Tax:-Frequently-Asked-Questions.

[102] JUDITH A. JOHNSON, CONG. RESEARCH SERV., R42130, FDA REGULATION OF MEDICAL DEVICES 22–23 (2012).

[103] *Id.*

[104] *Id.* at 23.

[105] PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 329–30 (2003).

[106] FRAN HAWTHORNE, INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT 46–47 (2005).

[107] *Id.*

[108] *Id.*

[109] *Id.*

[110] *Id.*

The MDAs took several steps to clarify FDA's power and procedures when dealing with medical devices. First, the MDAs set a definition for "device" that would distinguish a medical device from both a drug[111] and an unregulated product.[112] In basic terms, the MDAs clarified that the distinguishing factor between a medical device and an unregulated product was whether the manufacturer of the product made any medical claims.[113] As this Note will later discuss, Scanadu tried to evade this definition of medical device by explicitly saying the Scout made no medical claims. As the case law has clarified, however, regardless of this statement, the Scout is a medical device.[114]

Second, the MDAs codified general controls regulating all medical devices.[115] Included in these general controls are the requirements that a medical device cannot be adulterated or misbranded and must meet registering, listing, recordkeeping, import, and export requirements.[116] This Article will later explain how Scanadu failed to follow these general controls when shipping the Scout because, at the time, the Scout was an adulterated or misbranded medical device.[117]

Third, the MDAs defined three classes of medical devices.[118] FDA categorizes all devices into one of these three classes based on the risk that they pose to the public.[119] A device's classification affects what the manufacturer is required to submit to FDA before the device can be sold to consumers and what regulations the product is subject to after the product has been put on the market.[120]

Class I encompasses the lowest risk devices, such as elastic bandages and examination gloves.[121] In most cases, FDA only requires the manufacturer of a Class I medical device to register it before selling it.[122] However, in rare instances, FDA specifically requires the manufacturer to submit a 510(k), an application for approval,[123] before marketing the Class I device.[124] It is also rare for FDA to impose regulations on Class I devices beyond the general controls: ninety-five percent of Class I devices are exempt from special regulatory requirements.[125]

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[111] The MDAs separated a medical device from a drug by declaring that a medical device "does not achieve its primary intended purposes through chemical action within or on the body." 21 U.S.C.A. § 321(h) (West 2014).

[112] JOHNSON, *supra* note 102, at 23.

[113] Bruce D. Armon, *FDA Regulatory Scheme*, *in* BRINGING YOUR MEDICAL DEVICE TO MARKET 137, 139–40 (John B. Reiss & Bruce D. Armon, eds., 2006); *see also* 21 U.S.C.A. § 321(h) ("The term 'device'. . . means an instrument . . . which is--(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body.").

[114] *See infra* Part IV.A.1.

[115] 21 U.S.C.A. § 331; Armon, *supra* note 113.

[116] Armon, *supra* note 113.

[117] *See infra* Part IV.A.2

[118] United States v. Endotec, Inc., 563 F.3d 1187, 1189 (11th Cir. 2009).

[119] *Id.* (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 476 (1996)).

[120] JOHNSON, *supra* note 102, at 4–7.

[121] *Id.*

[122] *Id.*

[123] For an explanation of 510(k) see *infra* Part III.B.1.

[124] JOHNSON, *supra* note 102, at 4–7.

[125] Armon, *supra* note 113, at 140.

Class II devices pose a moderate risk, and, accordingly, FDA may subject these devices to special controls.[126] Power wheelchairs and infusion pumps are examples of Class II devices.[127] Most companies seeking to sell a Class II device must submit a 510(k) to FDA before marketing the device, although FDA has the discretion to exempt some Class II devices from this requirement.[128] FDA has the authority to levy "device-specific" regulations,[129] but generally these special controls include "postmarket surveillance, patient registries, development and dissemination of guidelines."[130] FDA currently imposes special controls on fifteen percent of all Class II medical devices.[131]

A Class III medical device is a device that is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury."[132] This class includes heart valves and metal-on-metal hip joints.[133] FDA requires most Class III device manufacturers to obtain Premarket Approval (PMA)[134] before the device can be made available to consumers.[135]

More specifically, FDA requires an approved PMA for three types of Class III devices: 1) devices that are not substantially equivalent to devices that were already on the market prior to the enactment of the 1976 amendments; 2) devices that are required by federal regulation (listed in 21 C.F.R.) to provide a PMA; and 3) all "new" devices that are not substantially equivalent to any device currently on the market.[136] All other Class III devices may be approved using a 510(k).[137] When a new device enters the market, FDA automatically categorizes it as a Class III device.[138] In order to avoid having to obtain a PMA, a manufacturer of a new device may petition FDA to have the device reclassified as a Class I or Class II device.[139]

The Scout is a brand new device. Nothing like it has ever been made before. In fact, Scanadu is in the running for the Qualcomm X-Prize,[140] a competition to build the

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[126] *Id.* at 140–41.

[127] JOHNSON, *supra* note 102, at 4–7.

[128] *Id.*

[129] Riegel v. Medtronic, Inc., 552 U.S. 312, 319 (2008) (citing 21 C.F.R. § 360j(e)(1) (2007)).

[130] Armon, *supra* note 113.

[131] JOHNSON, *supra* note 102, at 5–6.

[132] Federal Food, Drug, and Cosmetic Act (FFDCA) § 513(a)(1)(C), 21 U.S.C.A. § 360c(a)(1)(C) (West 2014).

[133] JOHNSON, *supra* note 102, at 5.

[134] For an explanation of PMA see *supra* Part III.B.2.

[135] Armon, *supra* note 113, at 141.

[136] *Id.*; *see also PMA Approvals*, FOOD & DRUG ADMIN., http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm (last updated Jan. 13, 2015).

[137] JOHNSON, *supra* note 102, at 6–7.

[138] Armon, *supra* note 113. This policy applies unless the device is quite obviously a Class I device.

[139] JOHNSON, *supra* note 102, at 6 (citing FFDCA § 513(f)(2)).

[140] *Scanadu Scout*, *supra* note 13.

first "Medical Tricorder,"[141] the winner of which will receive a $10 million prize.[142] Given this novelty, the Scout was a Class III device when it held its crowdfunding campaign. As a Class III device, Scanadu was required to submit the Scout for PMA or for reclassification before introducing the Scout into interstate commerce. Scanadu did neither. FDA also did nothing to stop Scanadu's crowdfunding campaign or the initial shipment to contributors.

B. *Different Paths to the Market*

As mentioned above, FDA requires a company seeking to bring a medical device to market to go through different processes depending on the risk the device poses. Generally, the more risk the device poses, the more rigorous the approval process. This Part will provide a brief explanation of the different paths to market, which will provide some background on the options and responsibilities Scanadu had when first contemplating bringing the Scout to market.

1. *The 510(k)*

A 510(k), named after the applicable section of the FFDCA, is the conduit that most manufacturers of Class II devices use to get their product to market.[143] Through a 510(k), the manufacturer must show that its product is substantially equivalent to a device already on the market that statutorily does not require a PMA.[144] A device meets the requirements of substantial equivalence if it is shown to be "as safe and effective as the predicate device(s)."[145] The goal of a 510(k) is to show that "the device performs in a similar fashion to the predicate [device] under a similar set of circumstances."[146] Clinical studies are not usually required to establish this.[147] Besides providing information about the device's performance under specific conditions, a standard 510(k) includes information about the device's design, components, packaging, and labeling.[148]

Though far less rigorous than a PMA, the development of a 510(k) can still be quite expensive. A Stanford study found that the average cost of bringing a "low-to-moderate-risk 510(k) product from concept to clearance was approximately $31 million, with $24 million spent on FDA dependent and/or related activities."[149] In addition, FDA requires a $5,018 fee for the review of a 510(k).[150]

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[141] A medical tricorder is "a hand-held medical scanner that can take readings from a patient and then diagnose various conditions." *The Dream of the Medical Tricorder*, ECONOMIST (Dec. 1, 2012), http://www.economist.com/news/technology-quarterly/21567208-medical-technology-hand-held-diagnostic-devices-seen-star-trek-are-inspiring. The medical tricorder made its debut in 1966 on the science fiction television series *Star Trek*. *Id.* On the show, Dr. McCoy used a fictional version of the medical tricorder to diagnose patients. *Id.*

[142] *Overview*, QUALCOMM TRICORDER XPRIZE, http://tricorder.xprize.org/about/overview (last visited Feb. 19, 2015).

[143] JOHNSON, *supra* note 102, at 9.

[144] *Id.*

[145] *Id.*

[146] *Id.*

[147] *Id.*

[148] *Id.*

[149] MAKOWER ET AL., *supra* note 24, at 7.

[150] *MDUFA III Fees*, Food & Drug Admin., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm313673.htm (last updated Sept. 30, 2014).

2. *Premarket Approval*

FDA requires all companies seeking to sell a new or exceptionally risky device to first obtain PMA,[151] an arduous task.[152] "The FDA spends an average of 1,200 hours reviewing each application," which usually consists of multiple volumes of reports, descriptions of methods used, lists of component parts, manufacturing processes, and label specimens.[153] The standard PMA fee for fiscal year 2014 is $258,502.[154] But this fee is miniscule compared to the overall costs of developing a product and meeting all of the testing specifications. A Stanford study estimates that it costs on average $94 million to bring a Class III device requiring PMA to market, with $75 million of that going towards meeting FDA requirements.[155] Companies spend a large portion of this money on clinical trials, which present an additional set of regulations; most notably, companies must obtain preliminary approval, also known as an Investigational Device Exemption (IDE).

3. *Investigational Device Exemption*

A medical device manufacturer must obtain an IDE before shipping the device to clinical study participants.[156] The IDE fixes the PMA's "catch-22"; without this exception, companies could not ship the device across state lines for use in the clinical trials, which are required in order to obtain final approval.[157]

There are different requirements a company must meet when applying for an IDE, depending on the level of risk posed by the medical device being tested.[158] After obtaining an IDE, a manufacturer can lawfully ship a device for use in its clinical studies without complying "with other requirements of the FFDCA, such as registration and listing."[159] As this Note will discuss later, Scanadu did not obtain an IDE before launching its crowdfunding campaign and promising contributors the opportunity to participate in its clinical trials. Even if it had, however, Scanadu's strategy of obtaining its test subjects through its crowdfunding campaign poses a moral hazard that FDA should address.

IV. SCANADU CONTRAVENED FDA REGULATIONS

In selling the Scout through its crowdfunding campaign, Scanadu evaded all of the detailed regulations explained above that were designed specifically to protect the health and safety of consumers. This Part will explain which specific regulations Scanadu contravened and how Scanadu's actions are directly in conflict with the overall purpose and mission of FDA.

Scanadu planned to ship its prototype of the Scout to thousands of its crowdfunding campaign donors in March of 2014.[160] At that time, Scanadu had not yet received—or

[151] JOHNSON, *supra* note 102, at 11.

[152] *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008).

[153] *Id.* at 318.

[154] *MDUFA III Fees*, *supra* note 150.

[155] MAKOWER ET AL., *supra* note 24, at 7.

[156] *Device Advice: Investigational Device Exemption (IDE)*, FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ (last updated June 19, 2014) ("All clinical evaluations of investigational devices, unless exempt, must have an approved IDE *before* the study is initiated.").

[157] *Id.*

[158] *See infra* Part IV.B.1.

[159] JOHNSON, *supra* note 102, at 12.

[160] *Scanadu Scout*, *supra* note 13.

even applied for—FDA approval.[161] Scanadu's crowdfunding campaign created two groups of contributors: those who opted to participate in the Scout's clinical trials (participants) and those who did not (non-participants).[162] Each group poses separate and unique legal issues that will be addressed in turn.

A. *The Non-Participants*

Scanadu's actions in regards to the non-participants poses a legal issue because, in shipping the Scout to this group, Scanadu moved an "adulterated or misbranded" medical device in interstate commerce as prohibited by the FFDCA.[163] To establish a violation of this statute, which is codified at 21 U.S.C. § 331(a), the Government must show three things: (1) the product is a "device" as defined in the FFDCA; (2) the product is an "adulterated or misbranded" device; and (3) the product moved in interstate commerce.[164] Under the FFDCA, a medical device is adulterated if "it is required to receive premarket approval from the FDA but moves in commerce even though it did not receive premarket approval."[165]

In plain language, it is a violation of the FFDCA to sell an unapproved Class III medical device to someone in another state.[166] That is exactly what Scanadu did when it held its crowdfunding campaign and sold the Scout to consumers who would not opt to participate in the clinical trials. The following three subsections elaborate on how Scanadu's actions meet the elements for a violation of this statute.

1. *The Scout Is a Medical Device*

The Scout is unquestionably a medical device as defined by the FFDCA. Scanadu tried to sidestep FDA regulation by calling the Scout a "research tool" instead of a medical device.[167] The Scout's crowdfunding campaign rhetoric laid the foundation for avoiding the regulation: "We are creating a medical-grade device, which is not yet fully accurate and not FDA-approved. Hence this is not a medical device . . . and makes no medical claims."[168] Scanadu further asserted that "[a]s a research tool, the product will not pose any risk to users and can be used to collect, store and display all your information, but without making specific disease diagnosis."[169]

This linguistic manipulation should not automatically free Scanadu from the purview of FDA regulatory scheme. The plain language of the regulation, the case law interpreting the statute, and the purpose and goals of FDA's regulations demonstrate why the Scout is a medical device and why Scanadu should not be able to evade FDA by calling the Scout a "research tool."

While saying that the Scout makes no "medical claims," Scanadu also maintains that it measures body temperature, blood pressure, heart rate, and more. All of the traditional devices that measure these same vital signs—a thermometer,[170] a sphygmomanometer,[171]

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[161] *Id.*

[162] *Id.*

[163] United States v. Endotec, Inc., 563 F.3d 1187, 1190 (11th Cir. 2009).

[164] United States v. Universal Mgmt. Servs., Inc., 191 F.3d 750, 754 (6th Cir. 1999).

[165] 563 F.3d at 1190.

[166] *Id.*

[167] *Scanadu Scout*, *supra* note 13.

[168] *Id.*

[169] *Id.*

[170] 21 C.F.R. § 880.2920 (2014).

[171] *Id.* § 870.1120.

even a stethoscope[172]—are all considered medical devices. The FFDCA defines "device" as an instrument "intended for use in the diagnosis . . . cure, mitigation, treatment, or prevention of disease."[173] The factor courts consider most determinative of whether a product is a device is the "objective intent" of the product manufacturer:

[T]he intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.[174]

Because intent is the dispositive factor, whether the product actually diagnoses or treats a disease or condition has no affect on whether the product is subject to medical device regulations.[175]

In determining a manufacturer's intent, FDA is not constrained by the manufacturer's claim that its product is not a medical device.[176] The District of Minnesota spoke directly to this principle in United States v. Sybaritic, Inc.[177] In Sybaritic, FDA had issued a cessation order, demanding that the defendant, Sybaritic, Inc., stop selling its products because they were medical devices under the FFDCA and had not been approved for sale under the applicable FDA regulations.[178] Sybaritic argued that their products were not medical devices and thus did not have to comply with the regulations.[179]

In analyzing whether the products were medical devices, the Sybaritic court considered the "intended use of the product as determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source, including consumer intent."[180] The advertising promoting the defendants' products clearly stated that the products helped with weight loss, scar reductions, and wrinkle reduction.[181] The court found these health-related claims put the products squarely within the federal definition of medical device.[182] The defendant's bald contention that it was not selling medical devices nor making medical claims had no effect on the court's decision.[183]

FDA and federal courts have consistently held that the intent of the manufacturer and the consumer in purchasing and using the product is the critical factor in whether a product is considered a medical device.[184] Even when the product is unconventional, when the medical claims are not based off of modern science, or when the medical

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[172] *Id.* § 870.1875.

[173] 21 U.S.C.A. § 321(h) (West 2014).

[174] 21 C.F.R. § 801.4 (2014).

[175] *See id.*

[176] United States v. Sybaritic, Inc., 789 F. Supp. 2d 1160, 1165 (D. Minn. 2011).

[177] *Id.*

[178] *Id.* at 1163–64.

[179] *Id.* at 1165.

[180] *Id.*

[181] *Id.*

[182] *Id.* at 1165–66.

[183] *Id.* at 1165 ("Defendants argue that the Slimline POD, Slimline OXYPOD Deluxe, and the Alpha LED Oxy Lite–Spa are not 'devices' since the expert it retained pursuant to the consent decree declared they were not devices . . . . However, the Court notes that the consent decree contemplated that any decision of the expert would be subject to an audit, indicating that his determination was not final or binding on the FDA. Therefore, this reasoning is not persuasive.").

[184] *See* Ass'n of Am. Physicians & Surgeons, Inc. v. FDA, 226 F. Supp. 2d 204, 216 (D.D.C. 2002).

claims seem implausible, courts look at what manufacturers intend consumers to use the product for.[185]

The plaintiffs in Holistic Candlers and Consumer Association v. U.S. Food and Drug Administration disputed FDA's determination that the plaintiffs' ear candles were medical devices.[186] Ear candles are fabric cones dipped in wax that are "intended to remove excess ear wax."[187] Consumers are instructed to place one end of the candle in their ear and light the other end on fire; as it burns, the candle creates a vacuum to draw wax and other impurities from the ear.[188]

The ear candle manufacturers claimed the ear candles were not medical devices but rather a "natural holistic modality . . . intended to be used for relaxation, comfort, reduction of stress and for the natural furtherance of the well-being of the user."[189] Defendants provided affidavits from consumers testifying that they use ear candles only for relaxation and not for medical purposes.[190] The ear candle manufacturers, however, had advertised the products as improving "sinus congestion, colds, the flu, sore throats, earaches, ear infections, sinus infections, lymphatic congestion, [and] swollen glands."[191] FDA had determined these were medical claims and advised the ear candle manufacturer that they must cease selling the devices or remove the medical claims from all advertisements and labels.[192]

Federal courts have also held that "labels of disclaimer are not controlling, but are to be considered together with any extrinsic evidence of the device's intended use."[193] The Ninth Circuit, in Church of Scientology of California v. Richardson, affirmed a district court determination that the "Hubbard E-meter" was a medical device subject to FDA regulations.[194] The Hubbard E-meter is a "simple skin galvanometer that crudely measures changes in electrical resistance in the human body."[195] The Church of Scientology argued that the Hubbard E-meters were "not misbranded because they bear declamatory labels"; the E-meters were marked with the warning: "Not intended or effective for the diagnosis, treatment, or prevention of any disease."[196] The court concluded that these disclaimers held no weight in determining whether the products

[185] *See, e.g.*, FTC v. QT, Inc., 448 F. Supp. 2d 908, 912, 955 (N.D. Ill. 2006) *amended for reconsideration in part*, 472 F. Supp. 2d 990 (N.D. Ill. 2007) *aff'd*, 512 F.3d 858 (7th Cir. 2008) *and aff'd*, 512 F.3d 858 (7th Cir. 2008) (determining that the Q-Ray bracelet was a medical device, based primarily on its advertisements which claimed that the metal bracelet "provides immediate significant or complete relief from various types of pain"); United States v. Universal Mgmt. Servs., Inc., 191 F.3d 750, 755 (6th Cir. 1999) (concluding that the defendant's product, an electric gas grill igniter outfitted with a finger grip, was a medical device because the defendant marketed them as pain-relieving devices); United States v. One Unlabeled Unit, More or Less, of an Article of Device & Promotional Brochures, 885 F. Supp. 1025, 1027–28 (N.D. Ohio 1995) (finding that a vinyl-covered bed with audio speakers mounted on its side was a device because the defendants claimed the bed improved circulation and balance and "reduce[d] the need for insulin, reduced cholesterol, reduced arthritis pain").

[186] Holistic Candlers & Consumer Ass'n v. FDA, 770 F. Supp. 2d 156, 158 (D.D.C. 2011).

[187] FDA Important Alert: *Detention Without Physical Examination of Ear Candles*, FOOD & DRUG ADMIN. (June 20, 2013), http://www.accessdata.fda.gov/cms_ia/importalert_225.html

[188] *Id.*

[189] Brief of Appellant, 770 F. Supp. 2d 156 (D.D.C. 2011) (No. 11-5118), 2011 WL 3947231, at *36.

[190] *Id.*

[191] 770 F. Supp. 2d at 158.

[192] *Id.* at 157.

[193] Church of Scientology of Cal. v. Richardson, 437 F.2d 214, 218 (9th Cir. 1971) (citing Alberty Food Prods. v. United States 194 F.2d 463 (9th Cir. 1952)).

[194] *Id.*

[195] *Id.* at 216.

[196] *Id.* at 218.

were adulterated medical devices because there was clear evidence that the E-meters were intended for medical use.[197] The skin galvanometers measured "skin voltage by means of surface skin electrodes"[198] and were "used as tools in psychoanalysis, hypnotherapy, biofeedback, and behavior therapy."[199]

Although the Scout is far more technologically sophisticated that the Hubbard E-meter, the two products are the same in several respects. Like the Scout, the E-meters did not directly treat a condition, but rather measured some physical phenomenon occurring in the human body. The only possible purpose of the E-meter's measurements was medical in nature; no disclaimer could nullify this fact. The Scout similarly takes measurements that are undoubtedly for medical use. Therefore, Scanadu's assertion that the Scout makes no medical claims should be rejected.

In Church of Scientology, the Ninth Circuit made several other important points. First, the court disregarded the defendant's admission that the E-meters were "ineffective for any medical therapeutic purpose."[200] A product does not escape the definition of medical device simply because it is ineffective.[201] Second, the court rejected the defendant's argument that the E-meters could not cause harm to any user.[202] The court analogized the E-meter to the product at issue in *Drown v. United States*, the "Drown Radio Therapeutic Instrument."[203] The maker of the Drown Radio Therapeutic Instrument made many fantastical claims including that the device could cure breast cancer, treat "cirrhosis and carcinoma of the right kidney," and "prevent loss of speech and memory."[204] In *Drown*, the Ninth Circuit explained that "[w]hile the instruments may be harmless in themselves, their danger lies in the possibility that 'ignorant and gullible persons are likely to rely upon them instead of seeking professional advice for conditions they are represented to relieve or prevent.'"[205] This point made by the *Drown* court summarizes why even a relatively benign device still needs to conform to FDA regulations.

Scanadu's non-participating contributors are the exact "ignorant and gullible" people the *Drown* court was speaking about. The Scout purports to measure vital signs and it is likely that consumers intend to use the Scout to do just that. In fact, that is the only thing the Scout could be used for. If the Scout is not accurate or malfunctions, these consumers will be put at risk.

Scanadu might have wanted to tap into one of crowdfunding's most valuable resources—consumer feedback on a large-scale—before having to comply with FDA regulations. However, altering a medical device requires a second round of tests and

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[197] *Id.* Because of the obvious medical use, the skin galvanometer was later codified as a Class II medical device in the Code of Federal Regulations. 21 C.F.R. § 882.1560 (2014).

[198] 21 C.F.R. § 882.1560.

[199] Gretchen Reevy, ENCYCLOPEDIA OF EMOTION 281 (2010).

[200] Church of Scientology of Cal. v. Richardson, 437 F.2d 214, 217 (9th Cir. 1971).

[201] *Id.*

[202] *Id.*

[203] *Id.* (citing Drown v. United States, 198 F.2d 999, 1002 (9th Cir. 1952)).

[204] Drown v. United States, 198 F.2d 999, 1001 (9th Cir. 1952) ("The Drown Radio Therapeutic Instrument, the device whose sale resulted in her arrest, is represented as capable of eliminating a lump in the breast and preventing cancer therefrom; as efficacious in treating kidney and bladder complications, tipped uterus, extra kidney, painful urination, streptococcus in the urethra and the pyloric end of the stomach and bladder, cirrhosis and carcinoma of the right kidney, low function of the left suprarenal gland, pancreas, fibrous adhesions in the brain and meningeal tissue, brain sinus, cystic fluid in the brain and medulla, heart trouble, head pains and noises, explosions in right ear while falling asleep, constipation, pains in the lower back, abcesses, loss of speech and memory, worry, fear and nervousness, conditions of the colon and liver.").

[205] *Id.* at 1006 (citations omitted).

applications for approval,[206] and Scanadu likely sought to avoid the costs of having to go through the approval process multiple times. FDA does not allow purely consumer focused feedback on medical devices prior to approval because of the risks those devices pose.[207] Calling a product a "research tool" instead of a medical device does not negate the potential risk. Consumers who receive the Scout will undoubtedly use the device and use it for its clearly intended medical purpose. The Scout, therefore, falls squarely within the definition of medical device.

It is critical to acknowledge that the Scout is not simply a "research device" because medical devices—but not research devices—are required to undergo testing during which potential harmful side effects or defects can be spotted and prevented. The Thalidomide crisis can lend some insight into the possible consequences of skipping over this critical step when developing an experimental product like the Scout.

Chemie Grünenthal, a German company, invented Thalidomide and began selling it on the German market in 1957.[208] Chemie Grünenthal sold Thalidomide to Richardson-Merrell, through its principal, Vicks Chemical Company, in 1958.[209] Richardson-Merrell planned to sell the drug on the U.S. market as a sedative and as an anti-nausea medication to be taken during pregnancy.[210] The FFDCA at the time allowed pharmaceutical companies to distribute unapproved drugs to a limited number of "qualified experts" on the condition "that the drug was labeled as being under investigation."[211] Merrel shipped Thalidomide samples to 1,267 doctors for experimental use in early 1960, seven months before it sent its application to FDA seeking to officially market the drug.[212] FDA denied the application and made specific demands on the company to provide more data showing the drug was safe and effective, specifically in pregnant women.[213]

In November 1961, news broke in Europe of the severe birth defects that Thalidomide caused in babies whose mothers took the drug while pregnant.[214] Chemie Grünenthal quickly took the drug off the market, but the drug had already been on the market for four years with devastating results: an estimated 8,000 babies were born in European countries with severe deformities because of the drug, while several thousand more died in the womb.[215] FDA estimates there were about forty cases in the United States, all from Merrell's experimental release of the drug.[216]

The Thalidomide crisis is just one example of what can happen when a medical product is released for a limited use prior to regulatory approval. The current regulations

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[206] *Deciding When to Submit a 510(k) for a Change to an Existing Device*, FOOD & DRUG ADMIN. (Jan. 10, 1997), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm (last updated Sept. 5, 2014).

[207] *IDE Approval Process*, FOOD & DRUG ADMIN., http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/investigationaldeviceexemptionide/ucm046164.htm#non_sig_risk (last updated June 26, 2014) ("[C]onsumer preference testing, testing of a modification, or testing of a combination of devices if the device(s) are legally marketed device(s) [that is, the devices have an approved PMA, cleared Premarket Notification 510(k), or are exempt from 510(k)] AND if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk." (alteration in original)).

[208] HILTS, *supra* note 105, at 146–48.

[209] *Id.* at 149.

[210] *Id.* at 150.

[211] PAUL J. FELDSTEIN, The Politics of Health Legislation: An Economic Perspective 206 (3d ed. 2006).

[212] HILTS, *supra* note 105, at 151–52.

[213] *Id.* at 152–53.

[214] *Id.* at 155.

[215] *Id.* at 155, 158.

[216] *Id.* at 158.

were intended to prevent these types of disasters, but the regulations carry no weight if they are not followed in all applicable circumstances. The Scout may seem like an innocuous device, but that, in itself, is not a good reason to exempt the Scout from premarket regulation. By going through the statutorily proscribed vetting process, FDA can ensure the Scout is safe, accurate, and does not present other hidden risks for consumers.

2. *The Scout Is an "Adulterated or Misbranded" Device*

When Scanadu held its crowdfunding campaign, and subsequently shipped the device to its contributors, the Scout was not only a medical device, but also an "adulterated device" moving in interstate commerce, which is a violation of 21 U.S.C. § 331(a).[217] A device is adulterated under the FFDCA if "it is required to receive premarket approval . . . from the FDA but moves in commerce even though it did not receive this PMA."[218] Recall that the Scout is a Class III device requiring PMA because the Scout is a new device that has not been reclassified.[219]

3. *The Crowdfunding Campaign Introduced the Scout into Interstate Commerce*

By raising money through a reward/pre-purchase crowdfunding campaign model, Scanadu put the Scout into interstate commerce for commercial distribution. When the Scout was shipped to contributors, there was no doubt that Scanadu had introduced the device into interstate commerce. But the Scout was introduced into interstate commerce even before that. The crowdfunding campaign in itself introduced the device into interstate commerce, and thus was a violation of 21 U.S.C. § 331(a).

Scanadu's crowdfunding campaign advertised the Scout to thousands of consumers over the Internet. These consumers were located all across the nation and around the world. When a contributor made a contribution to the campaign through Indiegogo, the contributors' credit cards or PayPal accounts were charged immediately after the checkout process was completed.[220] When the campaign reached its goal, Scanadu was "legally bound to perform on any promise and/or commitment to Contributors (including delivering any Perks)."[221] A crowdfunder which cannot fulfill its promised perks must negotiate a "mutually satisfactory resolution" with contributors, "which may include refunding their Contributions."[222]

In other words, when a crowdfunder offers a product as a "perk" on a campaign page, and the contributor gives the designated amount needed to receive that perk, the crowdfunder and the contributor have entered into a contract. During the execution of the contract, the contribution is transferred across state lines and thus through interstate commerce.

The reward/pre-purchase model can also be framed as a donation. Indeed, many CF platforms describe the interaction between contributor and crowdfunder as a charitable donation. Indiegogo calls any product offered in exchange for a contribution a "perk"[223];

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[217] 21 U.S.C.A. § 331(a) (West 2014).

[218] United States v. Universal Mgmt. Servs., Inc., 191 F.3d 750, 754 (6th Cir. 1999).

[219] *See supra* notes 140–42 and accompanying text.

[220] *Indiegogo Playbook: After Your Campaign*, INDIEGOGO, https://go.indiegogo.com/playbook/life-cycle-phase/finishing-strong (last visited Feb. 18, 2015).

[221] *Terms of Use*, INDIEGOGO, http://www.indiegogo.com/about/terms (last visited Feb. 15, 2015).

[222] *Id.*

[223] *Indiegogo Playbook: After Your Campaign*, *supra* note 43.

Kickstarter calls them "rewards."[224] But many crowdfunders on both sites, and many others, refer to their campaigns as a means to pre-order their product, album, or film.[225] The academic literature also describes this crowdfunding model as a way of "pre-ordering" or "pre-selling" a product.[226]

While Scanadu never used the terms "pre-order" or "buy" on its campaign page, other language indicates Scanadu intended for the campaign to be a pre-ordering mechanism. For example, as the donation increased, the contributor was able to benefit from economies of scale: if the contributor gave $756 she would receive four Scouts, meaning each would "cost[ ] $189 instead of $199."[227] This explicit language used by Scanadu indicates an intention to sell the Scout through its crowdfunding campaign.

To make a donation, a "donor must transfer an ownership interest to the donee without consideration and with donative intent."[228] The Scanadu campaign contributions do not meet this definition because they were given in exchange for consideration: the obligation to deliver the Scouts or return the money. The contributions to Scanadu's crowdfunding campaign, then, are not donations but rather contracts for sale.[229] These contracts were executed during the crowdfunding campaign and resulted in transfers of money across state lines. Scanadu, therefore, introduced the Scout into interstate commerce.

Scanadu's actions satisfy all three elements of a violation of 21 U.S.C. § 331(a). The Scout is a "device" as defined in the FFDCA, and the Scout required PMA before being introduced into interstate commerce, yet Scanadu introduced it into interstate commerce without obtaining clearance.[230] This decision, to make the Scout available to consumers without any level of review by FDA, by definition put consumers at risk. Other medical device companies that are planning on using crowdfunding should realize and understand this reality.

Scanadu is just one example of a medical device company using crowdfunding. As crowdfunding continues to increase in popularity, more companies that are seeking to sell medical devices, devices that are potentially far more dangerous than the Scout, could use the pre-purchase model to distribute those devices to imprudent consumers. If successful, this strategy undermines FDA medical device regulatory scheme and causes undue risk.

Scanadu is not the only medical device company that has used crowdfunding to raise money pre-FDA approval. Biosense, the maker of the uChek, is following Scanadu's crowdfunding strategy.[231] The "uChek Universal" is a "mobile urinalysis system" that uses a smartphone camera to analyze urine dipsticks.[232] The uChek Universal system provides information about ten different analytes present in the tested urine. [233] This

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[224] *Kickstarter Basics: Kickstarter 101*, *supra* note 41.

[225] Search "pre-order" on http://www.indiegogo.com/ or http://www.kickstarter.com/.

[226] *See, e.g.*, Hemer, *supra* note 12, at 9.

[227] *Scanadu Scout*, *supra* note 13 (emphasis added).

[228] *See* RESTATEMENT (THIRD) OF PROPERTY: WILLS & OTHER DONATIVE TRANSFERS § 6.1(a) (2003).

[229] *See* CONTRACT, BLACK'S LAW DICTIONARY (10th ed. 2014).

[230] *See* United States v. Universal Mgmt. Servs., Inc., 191 F.3d 750, 754 (6th Cir. 1999).

[231] Brian Dolan, *uChek Aims to Follow Scanadu's Pre-FDA Crowdfunding Strategy*, MOBIHEALTHNEWS (July 23, 2013), http://mobihealthnews.com/24056/uchek-aims-to-follow-scanadus-pre-fda-crowdfunding-strategy/.

[232] *uChek: Technology*, BIOSENSE, http://www.biosense.in/uchek.html (follow "Technology" menu link on left side) (last visited Feb. 19, 2015).

[233] *General FAQs about uChek*, BIOSENSE, http://www.biosense.in/faqs.html (last visited Mar. 1, 2015). The uChek Universal is designed to measure "analytes like glucose, protein, ketones, urobilinogen, bilirubin, specific gravity, blood, pH, leukocytes and nitrites." *Id.*

information, which is presented and analyzed through the uChek smartphone app, can be used to diagnose and monitor a variety of conditions including diabetes and "many bladder, liver and kidney disorders."[234]

Interestingly, Biosense tried to put the uChek Universal on the market in April of 2013 and was admonished by FDA for doing so prior to obtaining FDA approval.[235] Biosense registered its smartphone application on April 5, 2013, and sold its first device in the United States on April 28, 2013.[236] FDA sent Biosense a warning letter on May 21, 2013, informing the company that it would have to obtain FDA clearance for the uChek system before making it available to consumers.[237] Biosense took the uChek off the market and turned to the crowd to gain the necessary funds to apply for FDA approval.[238] Biosense also negotiated with FDA and the two were able to come up with a compromise: FDA agreed to allow Biosense to sell the "uChek Lite," but not the uChek Universal, without first obtaining FDA clearance.[239] The difference between the uChek Lite and the uChek Universal is the uChek Lite does not measure blood or glucose.[240]

Biosense is still working toward obtaining clearance for the uChek Universal and has launched an Indiegogo campaign to help it do so.[241] The Indiegogo campaign gives contributors the option of purchasing the "uChek Original" for $25, the uCheck Universal for $84, and many multi-pack options.[242] The campaign also informed contributors that "[a]ll uChek devices would ship after CE[243] and FDA clearances."[244] The vital difference between the crowdfunding campaigns associated with the Scout and the uChek is the fact that Scanadu shipped the Scout to consumers before receiving FDA approval, while Biosense waited to ship the uChek until after FDA approved it. Biosense's solution, however, did not address an additional problem Scanadu's crowdfunding strategy poses: whether campaign contributors should participate in pre-market clinical trials.

B. *The Participants*

Scanadu's interactions with the contributors who opted to participate in the Scout's clinical trials pose another issue in addition to the violation for introducing adulterated devices into interstate commerce.[245] Allowing backers of a crowdfunded medical device

[234] *Id.*

[235] *See Letter to Biosense Technologies Private Limited Concerning the uChek Urine Analyzer*, FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm353513.htm (last updated June 24, 2014).

[236] Shiv Gaglani, *uChek Launches Indiegogo Campaign: Interview with CEO Myshkin Ingawale*, MEDGADGET (Aug. 7, 2013), http://www.medgadget.com/2013/08/smartphone-based-urine-analysis-interview-with-ucheks-myshkin-ingawale.html.

[237] *Id.*

[238] *Id.*

[239] *See id.*

[240] *Id.*

[241] Ki Mae Heussner, *Urine-analysis App Turns to Indiegogo to Help It Win FDA Clearance*, GIGAOM (July 30, 2013), http://gigaom.com/2013/07/30/urine-analysis-app-turns-to-indiegogo-to-help-it-win-fda-clearance/.

[242] *uChek Universal: The Medical Lab in Your Phone*, INDIEGOGO, http://www.indiegogo.com/projects/uchek-universal-the-medical-lab-in-your-phone?c=activity (last visited Nov. 18, 2013).

[243] "The CE marking (an acronym for the French 'Conformite Europeenne') certifies that a product has met EU health, safety, and environmental requirements, which ensure consumer safety." *CE Marking – Program Overview*, EXPORT.GOV, http://export.gov/cemark/eg_main_017268.asp (last updated Mar. 7, 2013).

[244] *uChek Universal: The Medical Lab in Your Phone*, *supra* note 242.

[245] Note that at the time Scanadu held the crowdfunding campaign, it did not know if anyone would opt into the clinical studies. No contributor would be given the chance to participate in the clinical trials until after they received the Scout in the mail. Technically then, every sale of the device via the crowdfunding

to become subjects in the device's clinical trials creates the type of conflict of interest that FDA avidly works to avoid.[246] Considering the potential for bias and the many alterative methods for obtaining test subjects, FDA should prohibit this practice.

A device company is usually required to obtain an IDE from FDA before conducting its clinical trials.[247] Scanadu failed to obtain an IDE before launching its crowdfunding campaign and promising contributors the opportunity to participate in the clinical trials. Even if Scanadu had obtained regulatory approval, FDA should prohibit these trials because of the potential conflict of interest they pose.

1. *Scanadu Should Have Obtained an IDE for Its Clinical Trial Participants*

As mentioned before, an IDE allows a company to ship a Class III medical device in interstate commerce before receiving PMA in order "to obtain the test data needed for approval."[248] The IDE provides strict guidelines that must be met during the clinical trials to ensure the continued safety of the user.[249] The IDE allows the shipment of unapproved devices only to "experts qualified by scientific training and experience."[250] More specifically, under the IDE, the "device has to be shipped . . . to physicians who will test the device in patients under controlled circumstances."[251]

Rather than shipping the device to experts or physicians, Scanadu is shipping the Scout directly to patients who could use the device for other purposes outside of the clinical studies.[252] Knowing this information, it is hard to see how the Scout is being shipped for purely investigational purposes or meeting the IDE requirements. Scanadu also missed one very important procedural requirement: a company wishing to obtain an IDE typically must apply for and obtain the IDE before "enrolling patients at the study site."[253]

The IDE guidelines require different levels of precautions based on a particular device's level of risk. A company developing a "significant risk device" must obtain an IDE from FDA and must have every one of the sites at which it plans to conduct

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campaign, and the subsequent shipment of those devices, was a violation of 21 U.S.C. § 331(a). *See supra* Part IV.A. When Scandau ran its crowdfunding campaign, its Indiegogo page read, "[w]hen you receive your Scanadu Scout™, you will also be receiving the Informed Consent document which will enable you to take part in the community, participate in our usability study, and help us define the final properties of the device." Charles Luzar, *Indiegogo Campaign Roundup: Home Health Monitoring, Crowdfunding Legal Costs, Help Kids With Autism*, CROWDFUND INSIDER (May 23, 2013), http://www.crowdfundinsider.com/2013/05/16032-indiegogo-campaign-roundup-home-health-monitoring-crowdfunding-legal-costs-help-kids-with-autism/. Scanadu has since modified this language to read, "[b]efore you are eligible to receive your Scanadu Scout™, you will also be receive [sic] information about the study and the Informed Consent document." *Scanadu Scout*, *supra* note 13.

[246] *See What We Do*, FOOD & DRUG ADMIN., http://www.fda.gov/aboutfda/whatwedo/ (last updated Aug. 5, 2014) ("FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable.").

[247] *See infra* Part IV.B.1.

[248] *See supra* Part III.B.3; United States v. Endotec, Inc., 563 F.3d 1187, 1200 (11th Cir. 2009).

[249] *See* 21 U.S.C.A. § 360j(g) (West 2014).

[250] 563 F.3d at 1201.

[251] *Id.*

[252] *Scanadu Scout*, *supra* note 13.

[253] *IDE Approval Process*, *supra* note 207; 21 C.F.R. § 812.2 (2014).

clinical studies approved by an institutional review board (IRB).[254] "Nonsignificant risk devices," on the other hand, do not require an IDE from FDA, but rather must obtain approval only from an IRB.[255] Diagnostic devices are exempt from obtaining an IDE from FDA altogether, if the testing:

1. is noninvasive;
2. does not require an invasive sampling procedure that presents significant risk;
3. does not by design or intention introduce energy into a subject; and
4. is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.[256]

Because it is intended to measure vital signs, the Scout would probably be classified as a diagnostic device. So long as other medically established devices confirmed the Scout's readings during the clinical trials, Scanadu might not have needed an IDE before conducting its clinical trials.

2. *Crowdfunding Campaign Contributors Should Not Be Allowed to Participate in the Crowdfunded Device's Clinical Trials*

The intricate details of Scanadu's clinical trials and whether they conform to FDA's IDE requirements are not clear. But for any type of device, diagnostic or not, significantly risky or not, an IDE is a way to get a device into the hands of consumers and obtain feedback during the development process legally, while still conforming with FDA regulations. But allowing individuals who have purchased a device through a crowdfunding campaign to then participate in the clinical trials for that device poses a different issue, one that FDA has not had to address before.

FDA allows medical device and pharmaceutical companies to advertise clinical trials directly to consumers.[257] "[A]dvertising that is intended to be seen or heard by prospective subjects to solicit their participation in a study, is not in and of itself, an objectionable practice."[258] FDA, however, has explicitly excluded several things from the definition of acceptable direct advertising, including "(1) communications intended to be seen or heard by health professionals . . . (2) news stories[,] and (3) publicity intended for other audiences, such as financial page advertisements directed toward prospective investors."[259] Scanadu's crowdfunding campaign is very similar in substance to this third prohibited item.

This prohibition against advertising clinical trials to prospective investors reflects FDA's unease with mixing clinical trials with financial interests. In addition, FDA requires individuals involved in the clinical trials process who have a financial stake in the trials to fully disclose their financial interest.[260] Specifically, 21 C.F.R. § 54 requires companies seeking approval of their medical device to disclose any financial interest held by clinical investigators who are conducting clinical trials for the market approval

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[254] *IDE Approval Process*, *supra* note 207 ("A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject.").

[255] *Id.* ("Nonsignificant risk devices are devices that do not pose a significant risk to the human subjects.").

[256] 21 C.F.R. § 812.2.

[257] MARY BERNADETTE OTT & GARY YINGLING, FOOD & DRUG ADMIN., GUIDE TO GOOD CLINICAL PRACTICES, APPENDIX III (2013).

[258] *Id.*

[259] *Id.*

[260] 21 C.F.R. § 54.1 (2014).

application.[261] FDA adopted this regulation out of concern that a financial investment could "affect the reliability of data submitted to FDA."[262]

FDA does not require disclosures of financial interests held by test subjects in clinical trials. Investigators and test subjects, admittedly, are in very different positions with different levels of control over the data that is produced during a clinical trial. However, FDA's concern about potential bias runs deep, and 21 C.F.R. § 54 casts a wide net to capture any possible prejudice.[263] The regulation requires that the applicant must identify not only every clinical investigator and their financial interest, but also "the spouse and each dependent child of the investigator or subinvestigator."[264] If an applicant fails to provide this information, FDA may refuse to file the application altogether.[265]

It would be infeasible to require applicants for FDA approval to provide this information for every single subject of a clinical study, as thousands of individuals will participate.[266] If only a few subjects in a clinical trial held a financial interest in the product, or in the sponsor of the study, it is unlikely that the data would be skewed. This assurance of impartiality begins to disappear, however, when large percentages of the subjects have an interest. This could be the result if the subjects are obtained through a crowdfunding campaign.

Considering the expansive scope of the disclosures FDA requires clinical investigators to make, it seems FDA wants to quash any chance of bias. Although the bias of the crowdfunder who is a subject in a clinical trial may be small, it is at least considerable enough that crowdfunders that have backed a medical device should be prevented from participating in the clinical trials. Many different things motivate individuals in their decision to contribute to a crowdfunding campaign.[267] In the context of the pre-purchase model, many backers are motivated to contribute because they will receive a product in return for their contribution.[268] Many funders are also motivated, however, to contribute to "ideas and businesses [they] believe in."[269]

The contributors to the Scanadu Scout campaign were not given the option to participate in the clinical trials until after they had received the Scout.[270] At that point, the decision to support Scanadu's work was no longer motivated by the desire to

[261] FOOD & DRUG ADMIN., GUIDANCE FOR CLINICAL INVESTIGATORS, INDUSTRY, AND FDA STAFF: FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS 1 (2013), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf ("The Financial Disclosure by Clinical Investigators regulation (21 CFR part 54) requires applicants who submit a marketing application for a drug, biological product or device to submit certain information concerning the compensation to, and financial interests and arrangements of, any clinical investigator conducting clinical studies covered by the regulation.").

[262] *Id.* at 2.

[263] *See id.*

[264] *Id.* at 2.

[265] *Id.* at 4.

[266] A clinical trial consists of multiple phases, with an increasing number of test subjects at each stage. Phase 1 will test 20–80 individuals, phase 2 will test 100–300 individuals, and phase 3 will test 1,000–3,000 individuals. *Inside Clinical Trials: Testing Medical Products in People*, FOOD & DRUG ADMIN., http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143531.htm (last updated Nov. 6, 2014).

[267] *See* Elizabeth M. Gerber, Julie S. Hui & Pei-Yi Kuo, *Crowdfunding: Why People Are Motivated to Post and Fund Projects on Crowdfunding Platforms* (2012), *available at* http://www.juliehui.org/wp-content/uploads/2013/04/CSCW_Crowdfunding_Final.pdf; Michel Harms, *What Drives Motivation to Participate Financially in a Crowdfunding Community?* (July 13, 2007) (unpublished master thesis, VrijeUniversitaet Amsterdam), *available at* http://ssrn.com/abstract=2269242.

[268] Jonathan Sandlund, *Crowdfunding Motivations—What Drives People to Invest?*, THECROWDCAFE (Mar. 18, 2013), http://www.thecrowdcafe.com/crowdfunding-motivations/.

[269] *Id.*

[270] *Scanadu Scout*, *supra* note 13.

receive the product. The contributors opting into the trials were motivated by something else, perhaps the desire to see the company and the product succeed. A crowdfunding campaign contributor is very similar to an investor. In the case of a medical device, the device will not be made available to the public at large unless the device is successful in the clinical trials. Contributors opting to be test subjects could be motivated by the desire to see the product reach the shelves or the desire to know that they made a good investment.

While the motivation of backers is unclear, the chance for prejudice is certain. To avoid this possibility, FDA should not allow medical device or pharmaceutical companies to solicit clinical trial subjects through a crowdfunding campaign. There are many other methods of direct advertising a company can use to obtain participants, so this policy should not create an unfair burden.

V. ENFORCEMENT

Crowdfunding is an effective strategy for raising capital and device companies should be able to use it, with some restrictions. Scanadu's crowdfunding campaign for the Scout highlights some of the areas where crowdfunding is at odds with FDA regulations. By making the Scout available to consumers before FDA cleared it, Scanadu violated an essential FDA regulation. If FDA does nothing to enforce the regulation, it will set a precedent whereby other companies will try to follow the Scanadu crowdfunding model, putting more consumers at risk.

FDA needs to review the risks posed by the pre-purchase crowdfunding campaign model and issue guidance to help companies comply with the regulations while still allowing them to take advantage of the benefits of crowdfunding. At the heart of these guidelines should be the option for device companies to "pre-sell" their device if the company makes it clear to contributors that they will not receive the product unless FDA has fully approved it. This is the strategy Biosense used.[271] This solution allows companies to benefit from the most popular and effective crowdfunding model, the pre-purchase model, while ensuring that consumers are not purchasing adulterated devices.

In addition, FDA should prohibit device companies from giving backers the option to participate in clinical trials as a "perk." Allowing the overlap of these two groups creates a moral hazard that may ultimately affect the safety and efficacy of the device. Considering the large number of clinical trial subjects, it would be infeasible to mitigate the potential bias that might result if this was allowed. Thus, it should not be an option at all.

Finally, FDA should promulgate a regulation that prevents CF platforms from allowing medical devices to be crowdfunded using a pre-purchase model without following the applicable FDA guidelines. CF platforms differ widely in their policies about crowdfunding medical devices.[272] Under the proposed regulation, sites like Indiegogo would have to carefully screen companies looking to crowdfund a medical device. FDA has limited resources to police market activities like crowdfunding campaigns. By adopting regulations that impart liability on CF platforms, FDA will gain an ally in its effort to protect consumers.

CF platforms are not experts in FDA regulations, but their ability to screen unlawful campaigns is evidenced by their detailed terms and conditions. If need be, crowdfunding

[271] *See supra* Part IV.A.3.

[272] For example, Kickstarter does not allow anyone to use its site to fund the development of a medical product. *See supra* notes 93–95 and accompanying text. Indiegogo, on the other hand, permits many medical device companies to use its platform. *See supra* Part II.B.

websites could charge medical device companies a higher percentage of the funds raised in their campaigns to pay for the extra level of review.[273] This regulation will help keep device companies and crowdfunding websites cognizant of, and accountable for, the potential risks created when medical devices are made available to consumers before they have been properly tested. These regulations could lead all-purpose CF platforms to forbid medical device companies from using their services. This will force device companies wishing to utilize crowdfunding to do so via their own websites, or through healthcare-specific CF platforms that, because of their focus, will be better equipped to screen unlawful campaigns.

VI. CONCLUSION

FDA's mission is both to protect consumers and advance innovation. If properly regulated, crowdfunding could help achieve both of these goals. While there has been a drop in medical device investment, companies in all sectors are increasingly using crowdfunding as a means to raise start-up capital. Thus, if used appropriately, crowdfunding could bring a new wave of investment to the medical device industry.

Using Scanadu as an example, this Article has shown that crowdfunding medical devices can pose a host of regulatory issues that FDA needs to be aware of. Medical device companies should be able to use the pre-purchase model, but should not be able to ship a device to consumers before FDA has approved it. The Scout seems like a relatively harmless device, but by requiring *all* new devices to receive approval, FDA can help ensure the continued safety of consumers. In addition, medical device companies should not be able to obtain their clinical trial participants through their crowdfunding campaign. Clinical trials are an important step in gaining FDA approval, but their power lies in providing untainted data on the safety and efficacy of a device. To maintain the purity of clinical studies, FDA should disallow those who have a conflict of interest, like crowdfunding campaign contributors, from being test subjects. In this way, FDA can stimulate investment and innovation in the medical device field while continuing to protect consumers.

[273] For example, Indiegogo collects four percent of the total amount raised if a crowdfunder exceeds its goal; if the crowdfunder does not meet its goal Indiegogo collects nine percent of the total amount raised. *Fees and Pricing*, INDIEGOGO, http://support.indiegogo.com/entries/20492953-fees-pricing (last visited Feb. 18, 2015).