A hand holding a magnifying glass over a group of people icons. The background is a blurred image of a crowd of people. The magnifying glass is positioned over a group of seven stylized human icons, highlighting them. The overall theme is crowd-funding or community support.

## THE CATCH 22 OF CROWDFUNDING FOR MEDICAL DEVICES: IS IT PRE-SELLING?

*Inventors and companies are always looking for alternative ways to raise capital for the development of their products, and crowdfunding is becoming a hot trend. But when it comes to medical devices, FDA does not generally allow for the marketing of a device prior to its clearance or approval. This article will walk you through the basics of crowdfunding, advertising and promotional requirements of the FDA and when the two paths cross.*

### CROWDFUNDING BASICS

Crowdfunding is the practice of asking for money to fund a specific goal, generally through a website dedicated to crowdfunding, from the general public. An individual or company seeking to utilize crowdfunding ("crowdfunder") must first have a project or product for which to raise money and will choose a crowdfunding website (CF platform), which will host the crowdfunding campaign.<sup>1</sup>

## THERE ARE FOUR BASIC FORMS OF CROWDFUNDING:<sup>2,3</sup>

1. Donation-based crowdfunding, where money is given with no expectation of anything in return.
2. Debt-based or lending model funding is a loan where contributors may receive a rate of return on their investment.
3. Equity-based funding, which is currently only available to “accredited” investors. Investors in this group must prove a yearly income in excess of \$200,000 (or \$300,000 when combined with a spouse’s income) or have a net worth of over \$1 million (excluding the value of their residence) and must have had that level of income or net worth for three years running. These investors receive equity in the company raising the capital in exchange for their contributions. The equity model is heavily regulated by the SEC and is not frequently used, either inside or outside the United States.
4. Reward-based/pre-sell funding where the donor receives something in return for the donation (a prototype, access to the final finished products at an earlier date, better price, a non-medical device gift, the naming of a project/product after them, or some other special benefit).

Crowdfunding of medical devices is still a gray area for FDA as many in the industry question if the practice of crowdfunding with reward-based returns is considered ‘pre-selling’ or ‘marketing’ the device in advance of clearance or approval. FDA considers any products that are distributed (interstate commerce) prior to clearance or approval as ‘adulterated’. Marketing activities prior to clearance without appropriate disclaimers (e.g., investigational or regulatory submission status) is considered misbranding and false or misleading labelling. Yet, several start-up companies have engaged in crowdfunding, using donation-based and reward-based methods, as a way to pay for the cost of developing medical devices and of conducting clinical or usability studies to support the remaining development activities and regulatory submission activities.

A 2015 review by STATnews noted “...16 crowdfunded campaigns have been launched over the past few years by entrepreneurs who essentially took advance orders for medical devices that they said they planned to get OK’d by the FDA.”<sup>4</sup> One of the ways the fundraising was justified was by clearly stating the development and regulatory status of the device. Information regarding the status of the company’s project with FDA would be included on the website, including statements related to the timing of planned submissions to the FDA or confirmation that the application was under review.

## CROWDFUNDED DEVICES

For this article we took a quick look at some of the companies, past and present, that have crowdfunded development of medical devices, as reported in public sources.

### CUR (PRONOUNCED “CURE”)

Cur is an over-the-counter, wearable medical device transcutaneous electrical nerve stimulation (TENS) unit which is indicated for the symptomatic relief and management of chronic intractable pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household work activities.<sup>5</sup> It has powered muscle stimulation (PMS) mode which is indicated to improve and facilitate muscle performance in healthy muscles. Cur was cleared in May 2016 (K160052), but received industry attention in 2015 for attempting to raise \$50,000 on its own website by asking for a \$149 donation in order to receive the device after FDA clearance.<sup>6</sup> After scrutiny, Cur updated its website to clarify that the crowdfunding campaign was to support the continuing development operations and the 510(k) notification, and that the device would not be shipped before FDA clearance.<sup>7</sup>

### SCANADU SCOUT

Scanadu has a couple of products in the pipeline, one for vitals and the other for urine testing. However, it is probably more well-known for its fast paced Indiegogo campaign in 2013 which raised \$1,661,988 USD from 8509 backers for its Scanadu Scout™. The Scout™, still not yet FDA cleared, is a small device that records a person’s vitals by placing the device on the forehead and transmitting the data to an app on a smart phone. It is intended to measure heart rate, skin temperature, oximeter, blood pressure, temperature, heart rate, and pulse oxymetry—all cuffless, wireless and in seconds.<sup>8</sup> Scanadu offered several levels of donation and investment, where backers could merely ‘stay informed’ or receive products after FDA clearance. Interestingly, Scanadu actually consented backers to be part of a usability study and receive an investigational device. With this, early adopters were able to receive products, before FDA clearance, and Scanadu could receive customer feedback and usability data. It was made clear that if a backer did not participate in the study, the device would be shipped post-clearance or investment funds returned.<sup>9</sup> Scanadu continues to have it noted on their company website and on their closed Indiegogo site, that they are not yet FDA cleared.



## AIRING

Airing is a company that is currently raising funds for the development of a hoseless, maskless, cordless micro-CPAP device for the treatment of apnea. Airing had raised \$1,624,136 as of July 2015 and is still taking investments. Investments range from receiving an update on the progress, to product vouchers that can be exchanged once the product is FDA cleared (and a doctor's prescription provided), to becoming part of the research panel or Skyping with the inventor. Airing is very clear on their Indiegogo website that product availability is subject to FDA clearance and doctor's prescription.<sup>10</sup>

## SNORE CIRCLE

Devices like Snore Circle, by WFLY Electronics, ride the crest of 'are they a medical device or not?' Most FDA cleared anti-snoring devices are intraoral devices or devices that create expiratory resistance to maintain upper airway pressure.<sup>11</sup> However, Snore Circle identifies snoring sounds with bone conduction and sound recognition technologies, and then "intervenes physically with micro sounds and micro vibrations at 54 levels to stop snoring and make you sleep better." At this time, WFLY Electronics does not have any disclaimers about awaiting FDA clearance, but had raised over \$200,000 as of September 2016.<sup>12</sup>

## MEDICAL DEVICES AND THEIR PROMOTION

So, what is a medtech company to do to pursue crowdfunding and stay within regulations? First, a thorough regulatory assessment of the device, its intended use and clinical claims should be performed to understand if the product is a medical device and if so, what its classification is.

*Per section 201(h) of the Federal Food Drug & Cosmetic (FD&C) <sup>13</sup>, a medical device is:*

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- 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 of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

*Medical devices are categorized into one of three classes, based on the degree of risk they present. These classes are as follows:*

### Class I – Lowest Risk

These devices pose the lowest risk, such as elastic bandages, manual toothbrushes and general instruments. Class I devices are subject to general controls.

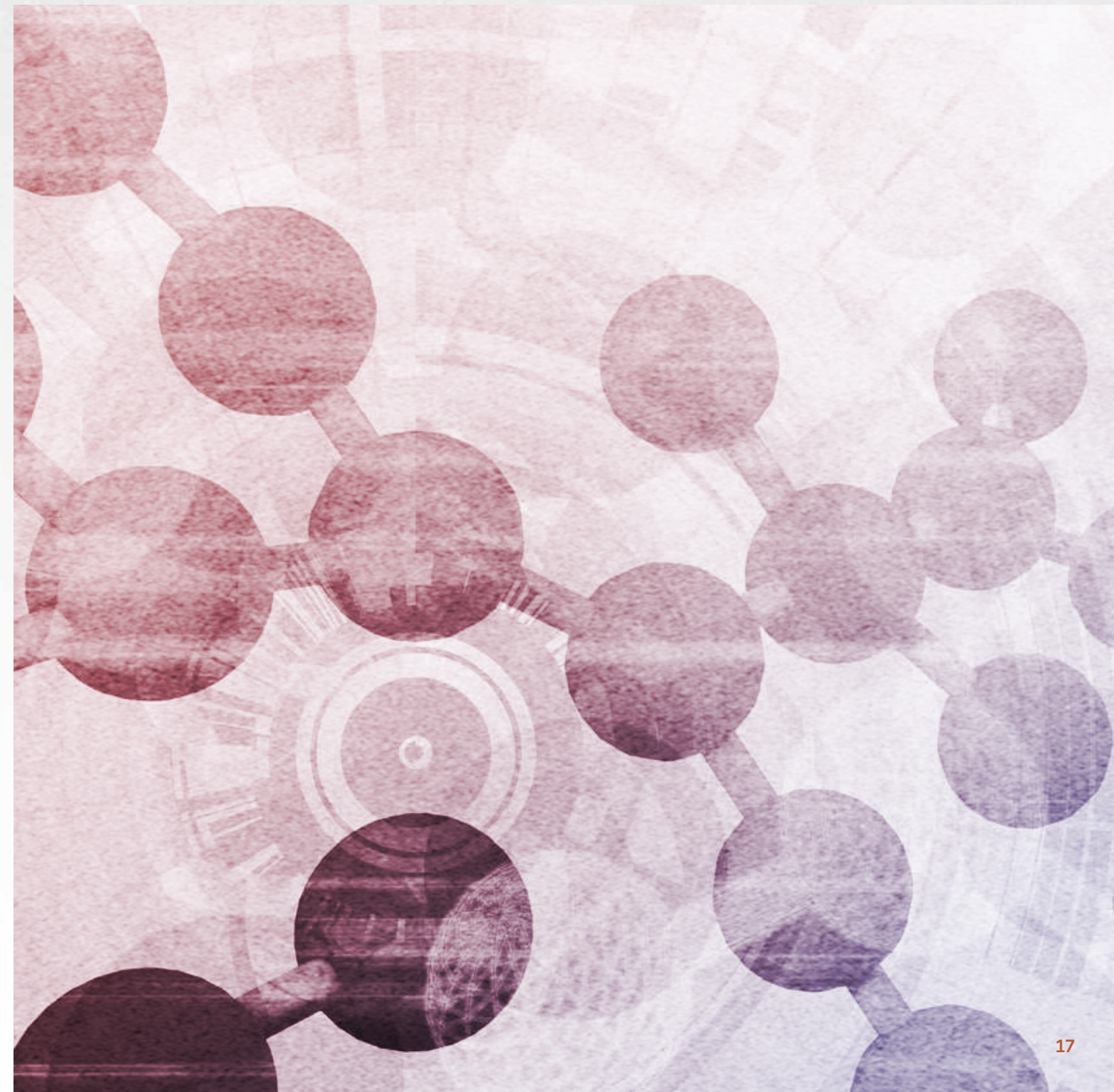
### Class II – Moderate Risk

Examples of Class II devices are syringes, IV catheters and non-invasive blood pressure monitors. Class II devices, which pose incrementally greater risk and for which general controls are not sufficient to provide reasonable assurance of safety and effectiveness, are subject to "special controls" in addition to general controls. Special controls may include labeling requirements, performance standards, post-market surveillance studies, or other controls the FDA deems necessary to provide reasonable assurance of the safety and effectiveness of the device.

### Class III – Highest Risk

The riskiest devices, such as some implants and life-supporting or life-sustaining devices, are placed in Class III and generally are subject to premarket approval (PMA), which means that an application must be submitted to and approved by FDA before the device may be legally

marketed. PMA applications must contain information that provides a reasonable assurance of the safety and effectiveness of the device for its intended use and generally include pre-clinical testing and clinical study data. An example of Class III device is a heart valve.





FDA does allow for companies to advertise or display devices subject to 510(k) with appropriate disclaimer, in the hope that FDA will conclude that the device is substantially equivalent to a pre-amendments device. However per FDA's Compliance Policy Guide Sec. 300.600, "...a firm may not take orders, or be prepared to take orders, that might result in contracts of sale for the device unless limited to research or investigational use."<sup>14</sup> So here is the Catch 22: How can crowdfunding with the reward-based model of the device be acceptable, and what does the device have to be used for? This policy does not discuss Class III devices and therefore

advertising or display of Class III products in advance of FDA approval should be avoided.

From a regulatory compliance perspective, the lowest risk models for crowdfunding are the donation, debt and equity investment models; donation being the easiest. These models do not provide the promise of a product voucher or the product itself after clearance. Scanadu and Airing have donation models that just 'keep you updated' about product development. Debt and equity investment models surely provide their own hurdles when conducting such transactions online, but will not be discussed here.

## If a company concludes the risk is worth the benefit, the company still must assure clear disclosure of how funded dollars will be used.

In the case of the reward-based model where the 'reward' is the actual device or a voucher for the device, this is higher risk as it could be interpreted as taking an order for a device that is not yet cleared or approved for distribution. There are some non-product rewards that were offered by the above groups that ranged from t-shirts to dinner with the inventor, but did not include a product. Others have considered a 'pay it forward' model, where the product would not be received by the backer but the product could be donated to a hospital/clinic of their choice after FDA clearance. At this time, FDA has not made written statement regarding crowdfunding, issued any warning letters to companies who have raised money through this process or taken any action to stop the practice. In an interview with the Boston Globe, William Maisel (acting director of the FDA's Office of Device Evaluation) said through a spokesman that medical device companies must follow the agency's marketing and advertising regulations regardless of how they raise funds, but he did not respond to questions about the legality of specific crowdfunding practices. Some postulate that FDA will not focus resources on regulating this practice unless it appears that patients are harmed.<sup>15</sup>

As noted earlier, some medical device companies have used the pre-selling model and FDA has not taken action; however this model is still considered to be a higher risk for products that have not yet been cleared. Risk must be evaluated on an individual basis for every device, in order for a company to determine if crowdfunding is an option. If a company concludes the risk is worth the benefit, the company still must assure clear disclosure of how funded dollars will be used (e.g., research, investigations, product development, etc.), apply appropriate disclaimers as to the status of the device, ensure diligent record keeping of funding transactions and keep a close eye on regulations as the landscape can change quickly. ■

<sup>1</sup> Colleen Smith, *Scouting for Approval: Lessons on Medical Device Regulation in an Era of Crowdfunding from Scanadu's "Scout"*, 70 Food & Drug L.J. 209, 212–13 (2015).

<sup>2</sup> *Id.*

<sup>3</sup> Deirdre Sullivan, *Crowdfunding for Medical Technology Development*, Farm Blog (July 31, 2014), <http://www.farmpd.com/Farm-Blog/bid/103510/Crowdfunding-for-Medical-Technology-Development> (last visited Oct. 17, 2016).

<sup>4</sup> Rebecca Robbins, *Crowdfunding of medical devices raises money — and questions*, Boston Globe (Sept. 8, 2015), <https://www.bostonglobe.com/business/2015/09/07/crowdfunding-medical-devices-raises-money-online-questions-the-fda-hasn-reviewed-these-medical-devices-yet-but-you-can-buy-them/RoVuxMgfefPufzuEKYzA4I/story.html> (last visited Oct. 17, 2016).

<sup>5</sup> K160052 510(k) Clearance Letter, [www.fda.gov](http://www.fda.gov); accessed October 17, 2016.

<sup>6</sup> Chris Newmarker, *Startup Tests FDA Limits with Crowdfunding Campaign*, Qmed (May 15, 2015), <http://www.qmed.com/news/startup-tests-fda-limits-crowdfunding-campaign> (last visited Oct. 17, 2016).

<sup>7</sup> Arielle Duhaime-Ross, *Medical device maker Cur adds disclaimers to crowdfunding site after questions about FDA rules*, The Verge (May 14, 2015), <http://www.theverge.com/2015/5/14/8609201/cur-fda-regulations-disclaimers-changes-website> (last visited Oct. 17, 2016).

<sup>8</sup> Scanadu, Indiegogo, <https://www.indiegogo.com/projects/scanadu-scout/#/> (last visited Oct. 17, 2016).

<sup>9</sup> Brian Dolan, *Scanadu production backed up, but FDA loophole ready to go*, Mobi Health News (Apr. 7, 2014), <http://www.mobihealthnews.com/31790/scanadu-production-backed-up-but-fda-loophole-ready-to-go/> (last visited Oct. 17, 2016).

<sup>10</sup> Airing, Indiegogo, <https://www.indiegogo.com/projects/airing-the-first-hoseless-maskless-micro-cpap-sleep-technology/#/> (last visited Oct. 17, 2016).

<sup>11</sup> FDA product codes LRK and OHP; [www.fda.gov](http://www.fda.gov); accessed October 17, 2016.

<sup>12</sup> Snore Circle, Indiegogo, <https://www.indiegogo.com/projects/the-world-s-smartest-anti-snoring-device-sleep/#/> (last visited Oct. 17, 2016).

<sup>13</sup> *Is The Product A Medical Device?*, FDA, <http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm> (last visited Oct. 17, 2016).

<sup>14</sup> ICPG Sec. 300.600, Issued 7/28/27, Reissued 10/1/80, 09/24/87; <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073888.htm>; accessed October 17, 2016.

<sup>15</sup> Deirdre Sullivan, *Crowdfunding for Medical Technology Development*, Farm Blog (July 31, 2014), <http://www.farmpd.com/Farm-Blog/bid/103510/Crowdfunding-for-Medical-Technology-Development> (last visited Oct. 17, 2016).

By Dawn Norman

