

BIOTECH CROWDFUNDING: HOW THE JOBS ACT ALONE CANNOT SAVE INVESTORS

Erica Wu*

Equity crowdfunding, the issuance of securities through online platforms to an unlimited number of investors, became a new legal source of capital for companies beginning in May 2016. Crowdfunding is one of several methods enacted by the JOBS Act through which emerging companies, or startups, can better access public capital. However, crowdfunding presents new risks to investors as many of the traditional securities law safeguards that protect investors are reduced or removed. Particularly in the biotech sector, crowdfunding investors are subject to increased information asymmetry, as ordinary individuals investing in complex scientific technologies may lack not only information about the company and the entrepreneur, but also the scientific background necessary to fully evaluate the technology itself. This Note analyzes the impact of the JOBS Act on biotech investing, focusing on the risks and protections available to crowdfunding investors, within as well as outside the bounds of the securities laws. This Note concludes with a proposal to integrate protections from FDA regulations and patent law into the crowdfunding rules.

| | | |
|-----|---|------|
| I. | Introduction..... | 1061 |
| II. | Background of the JOBS Act..... | 1066 |
| | A. Purpose of the JOBS Act..... | 1066 |
| | B. Summary of JOBS Act Provisions | 1068 |
| | C. Impact of the JOBS Act on the Biotech IPO Market..... | 1074 |

* J.D. Candidate 2019, Columbia Law School; B.A. 2013, Williams College. Many thanks to Professor Ronald Mann for his valuable insight and helpful comments in writing this Note. Additional thanks to the staff and editorial board of the *Columbia Business Law Review* for their assistance in preparing this Note for publication.

| | | |
|------|---|------|
| III. | Crowdfunding Risk and Protections | 1077 |
| | A. Challenges for Biotech Crowdfunding..... | 1077 |
| | B. Crowdfunding Investor Limits..... | 1083 |
| | C. Liability of Issuers and Intermediaries..... | 1087 |
| IV. | Supplementary Sources of Investor Protection from Patent and Administrative Law..... | 1090 |
| | A. Mandatory Disclosure Under Title III | 1090 |
| | B. Disclosure Requirements Relating to FDA Approvals | 1093 |
| | C. Patent Disclosure in Crowdfunding | 1100 |
| V. | Conclusion | 1102 |

I. INTRODUCTION

In 2015, Elizabeth Holmes topped the Forbes list of America's Richest Self-Made Women with an estimated net worth of \$4.5 billion.¹ A year later, Forbes lowered its estimate of Holmes' net worth to nothing,² and after another year, Holmes reportedly owed \$25 million to her company Theranos.³ A Silicon Valley biotech startup that Holmes founded at age nineteen, Theranos was once valued at \$9 billion and promised to revolutionize health care.⁴

¹ See Matthew Herper, *From \$4.5 Billion to Nothing: Forbes Revises Estimated Net Worth of Theranos Founder Elizabeth Holmes*, FORBES (June 21, 2016), <https://www.forbes.com/sites/matthewherper/2016/06/01/from-4-5-billion-to-nothing-forbes-revises-estimated-net-worth-of-theranos-founder-elizabeth-holmes/#20db9ab53633> [https://perma.cc/HP8Q-UPRH].

² See *id.*

³ See Anita Balakrishnan, *Founder Elizabeth Holmes Reportedly Owes Theranos About \$25 Million*, CNBC (Apr. 6, 2017, 8:12 AM), <https://www.cnbc.com/2017/04/05/founder-elizabeth-holmes-reportedly-owes-theranos-about-25-million.html> [https://perma.cc/5JUW-L39S].

⁴ See Nick Bilton, *Exclusive: How Elizabeth Holmes's House of Cards Came Tumbling Down*, VANITY FAIR (Oct. 2016), <https://www.vanityfair.com/news/2016/09/elizabeth-holmes-theranos-exclusive> [https://perma.cc/A8AT-8NLM]; see also Nick Stockton, *Everything You Need to Know About the Theranos Saga so Far*, WIRED (May 4, 2016, 8:00 AM) <https://www.wired.com/2016/05/everything-need-know-theranos-saga-far/> [https://perma.cc/2EB5-T72G].

Accumulating enormous amounts of funding from private investors, Theranos's technology would supposedly diagnose dozens of diseases with a pinprick of blood.⁵ However, in late 2015, the Wall Street Journal published an article exposing that the device produced inaccurate diagnoses and that Theranos relied on another company's traditional machines to run its tests.⁶ A series of other media outlets reported more issues with Theranos's science and its business,⁷ eventually leading to formal dissolution of the company and criminal charges against Holmes and other executives.⁸ All-in-all, major investors in Theranos lost nearly \$1 billion.⁹

The rapid and highly publicized rise and fall of Holmes and Theranos suggested that biotech investing could suffer, with startups facing more skepticism or a higher burden of proof of potential success at the early stages of financing. Some emphasized how Theranos was the exception rather than the rule, though, pointing out an unusual disparity between the level of hype and the paucity of available information surrounding the technology, reduced regulation of diagnostics compared to drugs, and funding sources from venture capitalists less experienced in life sciences.¹⁰ Nevertheless,

⁵ See Stockton, *supra* note 4.

⁶ *Id.*

⁷ *Id.*

⁸ See John Carreyrou, *Blood-Testing Firm Theranos to Dissolve*, WALL ST. J. (Sept. 5, 2018, 12:10 AM), <https://www.wsj.com/articles/blood-testing-firm-theranos-to-dissolve-1536115130> (on file with the *Columbia Business Law Review*).

⁹ See *id.*

¹⁰ See, e.g., Ben Popken, *How \$9 Billion Startup Theranos Blew Up and Laid Off 41%*, NBC NEWS (Jan. 6, 2017, 2:37 PM), <https://www.nbcnews.com/business/consumer/how-9-billion-blood-testing-startup-theranos-blew-n671751> [<https://perma.cc/V2RL-PP7J>]; Lydia Ramsey, *'The Outlier Thing Didn't Work Out' — Biotech CEOs Reflect on Theranos' Impact on the Industry*, BUS. INSIDER (Jan. 30, 2017, 1:55 PM), <https://www.businessinsider.com/was-there-a-theranos-effect-in-biotech-2017-1> [<https://perma.cc/6YLF-ZYQM>]; Randall Stross, *Don't Blame Silicon Valley for Theranos*, N.Y. TIMES (Apr. 27, 2016), <https://www.nytimes.com/2016/04/27/opinion/dont-blame-silicon-valley-for-theranos.html> [<https://perma.cc/H3PK-KMMS>] (noting that life science

the Theranos scandal is illustrative of the challenges that biotech startups face in attaining financing. In biotech, compared to other industries, the disparity between the sophistication of entrepreneurs and investors can be especially pronounced due to the scientific and technical background required to understand and develop a biotech product. While traditional life science venture capital firms hire investors with M.D.s and Ph.D.s, investors without subject matter expertise occasionally give significant funding to biotech startups that may not actually be supported by legitimate scientific evidence.¹¹

Ordinary individuals now have the opportunity to inject capital into new biotech companies following the passage of the Jumpstart Our Business Startups Act (the “JOBS Act” or the “Act”) in April 2012.¹² The Act was designed to stimulate economic growth by improving access to capital for startups and small companies with total annual gross revenues of less than \$1 billion, which are referred to in the Act as “emerging growth companies” (“EGCs”).¹³ Part of the capital tapped into by biotech startups following the passage of the JOBS Act is from “unaccredited investors”—ordinary individuals, as opposed to private equity firms and venture capitalists—who can now invest in startups with greater ease and without the traditional securities law safeguards.¹⁴ Specifically, Title III of the JOBS Act (the “Crowdfunding provision” or “Title III”) legalized the “online sale of securities to an unlimited number

venture capital firms refused to invest in Theranos; those who invested in Theranos were not individuals with expertise in the medical and science fields).

¹¹ See Stross, *supra* note 10.

¹² Jumpstart Our Business Startups Act, Pub. L. No. 112-106, 126 Stat. 306 (2012) (codified as amended in scattered sections of 15 U.S.C.).

¹³ Jesse Scott, Note, *The JOBS Act: Encouraging Capital Formation but Not IPOs*, 7 J. BUS. ENTREPRENEURSHIP & L. 367, 374–75 (2014).

¹⁴ Darian M. Ibrahim, *Equity Crowdfunding: A Market for Lemons?*, 100 MINN. L. REV. 561, 570–71 (2015); see also Brian Farnkoff, *Crowdfunding for Biotechs: How the SEC’s Proposed Rule May Undermine Capital Formation for Startups*, 30 J. CONTEMP. HEALTH L. & POL’Y 131, 134–35 (2013).

of investors (i.e., [.] a large ‘crowd’) in small amounts using the power of social media.”¹⁵ The Crowdfunding provision permits entrepreneurs to offer and sell securities without activating the registration requirements of the Securities Act of 1933 (the “Securities Act”).¹⁶ Harnessing the power of the internet and social media, Title III is directed at transforming financing for companies who otherwise would face significant difficulty attracting it.¹⁷ However, the Crowdfunding provision may allow for bad actor companies, similar to Theranos, to seek substantial amounts of funding from ordinary individuals investing through crowdfunding. In the biotech sector, a greater disparity in market and product knowledge between investors and companies, as compared to other industries, may expose individual investors to enhanced risk of fraud.

This Note analyzes the various legal protections available to potential investors in “biotech startups,” a term used here to refer to all small companies focused on creating medical drugs and devices.¹⁸ Traditionally, the term “biotech companies” referred to companies focused on creating medicinal drugs with a biological (living-organism) basis, as opposed to pharmaceutical companies, whose drug products were small molecules with a chemical (synthetic) basis.¹⁹

¹⁵ Farnkoff, *supra* note 14, at 134–35.

¹⁶ *Id.*

¹⁷ *Id.* at 133–35; *see also* Krystine Therriault, *What Is Equity Crowdfunding?*, CROWD CRUX, <https://www.crowdcru.com/what-is-equity-crowdfunding/> [<https://perma.cc/2RVC-4VMF>].

¹⁸ Though Theranos is discussed throughout this Note, its product falls under the category of a diagnostic, instead of a medical drug or device referenced here by the term “biotech.” While the regulatory framework governing Theranos as a diagnostics company differs from that which governs biotech startups, *see infra* note 176, as a small company with a product in the medical field, Theranos is a relevant example showcasing financing issues concerning biotech startups and their investors.

¹⁹ *See* Troy Segal, *Biotech Vs Pharmaceutical Company*, INVESTOPEDIA (Jan. 8, 2018, 8:29 PM), <https://www.investopedia.com/ask/answers/033115/what-difference-between-biotechnology-company-and-pharmaceutical-company.asp> [<https://perma.cc/2BEQ-FKC3>].

Biotech companies were generally more focused on research and development, while pharmaceutical companies centered on manufacturing on a larger, commercial scale.²⁰ As such, biotech companies faced higher costs and a greater time investment to develop and test a product.²¹ Recently, the line between the two industries has become increasingly blurred, not only in terms of the science, but also in terms of the competitive landscape.²² While big biotech has emerged, with similar traits to big pharma, this Note focuses on investment in smaller startup companies developing all types of medical drugs and devices.²³

Previous literature has discussed the potential for fraud through crowdfunding but has specifically focused on the protections set out in Title III.²⁴ This Note argues that other areas of the law provide supplementary, though still insufficient, protection for ordinary individuals seeking to invest in biotech under the Crowdfunding provision. Part II of this Note provides a summary of the history and provisions of the JOBS Act. Part III describes the risks crowdfunding poses in exposing investors to bad actors, particularly in the biotech industry, and the protection measures already available under Title III. Part IV describes how administrative law—through Food and Drug Administration (“FDA”) regulations and approvals—and patent law serve as additional backstops to investor protection. Part IV demonstrates that the timing and public availability of FDA approval and patent information prevent such measures from effectively notifying and protecting investors. This Note concludes with a proposal

²⁰ See Hejab Azam, *Pharmaceutical Vs Biotech: Chemistry vs Biology*, PATSNAP (Jan. 12, 2017, 11:00 AM), <https://blog.patsnap.com/pharmaceutical-vs-biotech-chemistry-vs-biology> [<https://perma.cc/MXQ7-HWG7>].

²¹ See *id.*; Segal, *supra* note 19.

²² Meghana Keshavan, *Big Biotech is Here — And It’s Starting to Look a Lot Like Big Pharma*, STAT (June 6, 2016), <https://www.statnews.com/2016/06/06/big-biotech-pharma/> [<https://perma.cc/G4RL-CDFV>].

²³ *Cf. id.*

²⁴ See *generally* Farnkoff, *supra* note 14; Ibrahim, *supra* note 14.

that biotech startups be required to disclose FDA approval and patent information on the investing platforms as a means to better protect investors against the heightened risk of fraud in the biotech industry.

II. BACKGROUND OF THE JOBS ACT

A. Purpose of the JOBS Act

To fund a new business, entrepreneurs may turn to private sources of capital—angel investors, venture capitalists, and private equity financiers—all of whom seek a high rate of return on their investments.²⁵ The initial public offering (the “IPO”) market, as a result, is particularly important to startups and EGCs because it is one of three major methods of exit for investors, the others being merger or acquisition.²⁶ The IPO market offers many advantages over merger and acquisition (“M&A”) markets: access to capital to fund growth or repay debt; increased liquidity for existing owners to exit; and public currency to finance acquisitions.²⁷ The IPO process also provides exposure and branding through media and analyst coverage as well as stock option benefits for current and future employees.²⁸ Furthermore, going public is often accompanied by job creation, while M&A can lead to downsizing in order to eliminate redundancy.²⁹

However, in the two decades between 1990 and 2011, the ratio of IPOs to M&A exits dropped dramatically.³⁰ Between 2001 and 2010, seventy-five percent fewer EGCs went public than between 1991 and 2000, and the average age of companies going public was higher than during the previous

²⁵ Scott, *supra* note 13, at 368.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ IPO TASK FORCE, REBUILDING THE IPO ON-RAMP: PUTTING EMERGING COMPANIES AND THE JOB MARKET BACK ON THE ROAD TO GROWTH 1, 6 (2011), https://www.sec.gov/info/smallbus/acsec/rebuilding_the_ipo_on-ramp.pdf [<https://perma.cc/9R6L-W995>].

³⁰ *See id.* at 7 chart E.

decade.³¹ The IPO Task Force, formed in 2011 and comprised of “venture capitalists, experienced CEOs, public investors, securities lawyers, academicians[,] and investment bankers,”³² identified several regulatory and market challenges that discouraged EGCs from going public.³³ Since the late 1990s, a series of new rules and regulations (including the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010) required that public companies adopt more stringent financing and accounting systems.³⁴ These rules and regulations came about in response to a series of crises and scandals at major public companies and constituted an attempt to restore confidence in the public markets.³⁵ This one-size-fits-all U.S. securities regulation scheme placed enormous compliance costs on companies contemplating an IPO.³⁶

For EGCs in particular, compliance demanded a substantial proportion of the company’s earnings and lowered the company’s market capitalization.³⁷ EGCs could not provide as much information to potential investors, making their stocks more difficult to understand and invest in, and investment banking practices thus shifted toward high-frequency trading of large-cap stocks instead of long-term investing in companies.³⁸ As a result, the IPO process became

³¹ *Id.* at 6.

³² *Id.* at 1.

³³ *Id.* at 8.

³⁴ *Id.* at 9

³⁵ *Id.*

³⁶ *Id.* at 8. The regulatory theory, which argues that federal regulatory choices are responsible for the reduction in EGC IPOs, is considered the most prominent theory in this area. Other theories focus on enforcement (public and private litigation), market structure (economic barriers), and economic scope (alternative outlets) as reasons for a stunted small IPO market. See Paul Rose & Steven Davidoff Solomon, *Where Have All the IPOs Gone? The Hard Life of the Small IPO*, 6 HARV. BUS. L. REV. 83, 84 (2016).

³⁷ IPO TASK FORCE, *supra* note 29, at 9.

³⁸ *Id.*

less attractive and more difficult for EGCs looking to exit their initial financing arrangements.³⁹

The IPO Task Force found that the high cost of regulatory compliance was the primary concern for pre- and post-IPO companies.⁴⁰ EGCs seeking an IPO needed to be ready to take on these costs and build up their compliance infrastructure one or two years before they expected to go public.⁴¹ In order to reduce these regulatory costs, facilitate capital formation, and stimulate the dwindling U.S. IPO market, Congress enacted the JOBS Act with a stated goal to “increase American job creation and economic growth by improving access to the public capital markets for emerging growth companies.”⁴² The JOBS Act reduces financial statement disclosure requirements (Title I), removes several prohibitions on advertising (Title II), allows for additional sources of capital from individual investors (Title III), creates a new class of exempted securities (Title IV), and changes Securities and Exchange Commission (“SEC”) registration thresholds (Titles V and VI).⁴³

B. Summary of JOBS Act Provisions

The JOBS Act’s central provision is the IPO on-ramp, found in Title I: Reopening American Capital Markets to

³⁹ *See id.*

⁴⁰ *Id.* (citing two surveys from 2011 which found that “the average cost of achieving initial regulatory compliance for an IPO [was] \$2.5 million, followed by an ongoing compliance cost, once public, of \$1.5 million per year.”).

⁴¹ *Id.*

⁴² Jumpstart Our Business Startups Act, Pub. L. No. 112-106, § 101, 126 Stat. 306, 306 (2012) (codified as amended in scattered sections of 15 U.S.C.); *see also* Rose & Solomon, *supra* note 36, at 84–85. The JOBS Act was enacted primarily to reduce the federal regulatory burdens in place for EGCs, such as part of the Sarbanes-Oxley Act of 2002, which required “public company auditors to attest to and report on management’s internal control over financial reporting,” though it also addressed market forces by loosening restrictions on research analysts. *Id.* at 85 n.7.

⁴³ *See* Rose & Solomon, *supra* note 36, at 85; Scott, *supra* note 13, at 374–85.

Emerging Growth Companies, by which Congress intended to ease the regulatory burden associated with going public for smaller companies.⁴⁴ Previously, companies with a market capitalization of less than \$75 million were exempt from a number of public disclosure requirements.⁴⁵ However, the exemption was not useful for many companies considering an IPO, as many of these companies were high-growth and venture-backed with a market capitalization outside this range.⁴⁶ Section 101 of the JOBS Act defines a new category of issuer, the EGC, as one with total annual gross revenues of less than \$1 billion during its most recent fiscal year.⁴⁷ The JOBS Act not only extends the disclosure exceptions to companies with a higher market capitalization, but it also provides a five-year qualifying limit, allowing the EGC to gradually ramp up reporting obligations within the five-year period after it goes public.⁴⁸ This on-ramp reduces the burdensome filing and compliance requirements for a wider range of companies.⁴⁹

EGCs now face accounting regulations more in line with those faced by private companies rather than those that apply to public companies.⁵⁰ EGCs are exempt from certain Sarbanes-Oxley accounting standards and from several financial performance and executive compensation disclosure requirements.⁵¹ They are not required to seek shareholder approval on a number of compensation-related provisions in

⁴⁴ See Scott, *supra* note 13, at 373–75.

⁴⁵ *Id.* at 374.

⁴⁶ *Id.*

⁴⁷ Jumpstart Our Business Startups Act § 101. In 2017, the SEC effectuated inflation adjustments required under Title I—that the SEC would index for inflation every five years—and increased the revenue threshold from \$1 billion to \$1.07 billion. Inflation Adjustments and Other Technical Amendments Under Titles I and III of the JOBS Act, 82 Fed. Reg. 17,545, 17,549 (Apr. 12, 2017) (to be codified at 17 C.F.R. pt. 210, 227, 229, 230, 239, 240, 249).

⁴⁸ See Scott, *supra* note 13, at 375.

⁴⁹ See *id.* at 374–75.

⁵⁰ *Id.* at 375.

⁵¹ *Id.* at 376.

the Securities Exchange Act of 1934 (the “Exchange Act”), which benefits founders and entrepreneurs who prefer to retain control over compensation after going public.⁵² The JOBS Act also facilitates communication about the EGC between management and potential investors, as well as with research analysts, during the IPO process, thus helping to value the company’s securities.⁵³

While Title I is geared toward IPOs, the remaining provisions of the JOBS Act are “devoted to expanding capital-raising options for smaller, private companies.”⁵⁴ Title II: Access to Capital for Job Creators addresses communication barriers, costs, and uncertainties for companies wishing to conduct private offerings under Rule 506 of Regulation D or Rule 144A.⁵⁵ Rule 506 and Rule 144A offerings make up the majority of private market offerings, and the aggregate capital raised through these two methods is comparable to, if not greater than, that raised through the public market.⁵⁶ Title II provides a registration exemption for general solicitation and advertising in securities transactions under Rule 506 and Rule 144A.⁵⁷

⁵² *Id.*

⁵³ *Id.* at 376–77.

⁵⁴ Tom Zanki, *JOBS Act Shows Mixed Progress at 5-Year Mark*, LAW360 (Apr. 6, 2017, 9:05 PM), <https://www.law360.com/articles/910544/jobs-act-shows-mixed-progress-at-5-year-mark> (on file with the *Columbia Business Law Review*).

⁵⁵ See *Eliminating the Prohibition Against General Solicitation and General Advertising in Rule 506 and Rule 144A Offerings*, 78 Fed. Reg. 44,771, 44,787–88, 44,797–98 (Sept. 23, 2013) (to be codified at 17 C.F.R. pt. 230, 239, 242).

⁵⁶ See SCOTT BAUGUESS, RACHITA GULLAPALLI & VLADIMIR IVANOV, *CAPITAL RAISING IN THE U.S.: AN ANALYSIS OF THE MARKET FOR UNREGISTERED SECURITIES OFFERINGS, 2009–2014*, 7 fig.1 (2015); see also Scott, *supra* note 13, at 380 (“The importance of Regulation D offerings is shown by the fact that they are one of the most—if not the most—often used offering vehicles. Within the Regulation D exemptions, Rule 506 is the most prevalent. . . . The Rule 144A market also plays a key role in capital formation.”).

⁵⁷ *Eliminating the Prohibition Against General Solicitation and General Advertising in Rule 506 and Rule 144A Offerings*, 78 Fed. Reg. at

As described previously, Title III: Crowdfunding allows businesses to use the internet and social media to sell securities to a large number of people in relatively small amounts.⁵⁸ These equity crowdfunding offerings provide individual investors with a share of the company's potential financial returns or profits, and the offerings must fall within the exemption created by the JOBS Act in order to avoid registration with the SEC.⁵⁹ Title III adds sections 4(6) and 4A to the Securities Act and exempts transactions involving the offer or sale of securities by an issuer if: (1) the total amount sold to all investors during the preceding twelve months does not exceed \$1 million; (2) the total amount sold to any single investor during the preceding twelve months does not exceed (a) the greater of \$2000 or five percent of the annual income or net worth of the investor if the annual income or net worth of the investor is below \$100,000, or (b) ten percent of the annual income or net worth of the investor if the annual income or net worth of the investor is \$100,000, up to a maximum aggregate amount sold of \$100,000; (3) the transaction is conducted through a broker or compliant

44,773–74; *see also* Scott, *supra* note 13, at 377–80. Rule 506 provides a registration exemption for offerings by an issuer “not involving any public offering” from registration under section 4(a)(2) of the Securities Act, with no limit on the dollar amount of securities. Eliminating the Prohibition Against General Solicitation and General Advertising in Rule 506 and Rule 144A Offerings, 78 Fed. Reg. at 44,772–73. Section 201(a)(1) of the JOBS Act removes the prohibition on general solicitation and advertising in transactions under Rule 506, provided that the purchasers are accredited investors and that the issuers take reasonable steps to verify that they are. *Id.* at 44,773. Rule 144A previously only provided a registration exemption for securities offered to actual qualified institutional buyers under section 4(a)(1) of the Securities Act. *Id.* Section 201(a)(2) of the JOBS Act amended Rule 144A by providing a registration exemption for securities sold, including through general solicitation and advertising, to all purchasers who the seller reasonably believes to be qualified institutional buyers. *Id.* at 44,773–74.

⁵⁸ Crowdfunding, 80 Fed. Reg. 71,387, 71,388 (May 16, 2015) (to be codified at 17 C.F.R. pt. 200, 227, 232, 239, 240, 249, 269, 274).

⁵⁹ *Id.* at 71,389.

funding portal; and (4) the issuer complies with disclosure and other requirements.⁶⁰

The exemption requires a number of disclosures to be filed with the SEC, provided to investors and the intermediary broker or funding portal, and made available to potential investors.⁶¹ The disclosures include the issuer's name, legal status, and physical and website addresses, as well as the names of the issuer's directors, officers, and stockholders holding twenty percent or more of the issuer's securities.⁶² The issuer must describe its business plan, financial condition, intended use of proceeds, target offering amount and deadline, updates to reaching the target amount, price or method of determining price, and ownership and capital structure.⁶³ Furthermore, the issuer must report its financial statements and operation results at least once per year to the SEC and investors.⁶⁴

The Crowdfunding provision restricts which types of issuers can benefit from the registration exemption—it excludes non-U.S. issuers, reporting companies, and investment companies.⁶⁵ The SEC can also issue rules and regulations to disqualify categories of issuers from eligibility; moreover, the JOBS Act requires the SEC to disqualify parties from reliance on the crowdfunding exemption based on their

⁶⁰ Jumpstart Our Business Startups Act, Pub. L. No. 112-106, §§ 302–303, 126 Stat. 306, 315–21 (2012) (codified as amended in scattered sections of 15 U.S.C.). In 2017, the SEC effectuated inflation adjustments required under Title III, as in Title I, *see supra* note 47, and increased the maximum offering amounts and investment limits. Inflation Adjustments and Other Technical Amendments Under Titles I and III of the JOBS Act, 82 Fed. Reg. 17,545, 17,549 (Apr. 12, 2017) (to be codified at 17 C.F.R. pt. 210, 227, 229, 230, 239, 240, 249).

⁶¹ Jumpstart Our Business Startups Act, Pub. L. No. 112-106, § 302, 126 Stat. 306, 315–21 (2012) (codified as amended in scattered sections of 15 U.S.C.).

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

disciplinary history.⁶⁶ In regards to advertisements and promotions, Title III prohibits issuers from (1) advertising the terms of the crowdfunding offering, except in order to direct investors to brokers or the funding portal, and (2) compensating third-party promoters, unless the promoter clearly discloses that the issuer is compensating it.⁶⁷

Title IV: Small Company Capital Formation directs the SEC to amend Regulation A and exempt certain offerings of up to \$50 million in any twelve-month period.⁶⁸ Regulation A previously exempted securities from most reporting requirements, but it was not widely used by issuers because the maximum amount of securities that the regulation permitted was quite low—\$5 million in a twelve-month period.⁶⁹ Now informally referred to as Regulation A+, the amended act provides another method for raising large amounts of capital exempt from registration requirements.⁷⁰ Section 401 of the JOBS Act amended section 18(b)(4) of the Securities Act to categorize compliant Regulation A+ securities as “covered securities,” so that state registration and qualification requirements are preempted if the securities are offered or sold on a national securities exchange or only to qualified purchasers.⁷¹ This expands the pool of potential investors.⁷²

Finally, Title V: Private Company Flexibility and Growth and Title VI: Capital Expansion permit private companies to

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.* at § 401; *see also* Scott, *supra* note 13, at 383; *Amendments to Regulation A: A Small Entity Compliance Guide*, U.S. SEC. & EXCHANGE COMMISSION (June 18, 2015), <https://www.sec.gov/info/smallbus/secg/regulation-a-amendments-secg.shtml> [<https://perma.cc/7CUS-NKWD>].

⁶⁹ *See* Press Release, SEC, SEC Adopts Rules to Facilitate Smaller Companies' Access to Capital (Mar. 25, 2015), <https://www.sec.gov/news/pressrelease/2015-49.html> [<https://perma.cc/YN63-MKJT>].

⁷⁰ *See id.*

⁷¹ *See* Amendments for Small and Additional Issues Exemptions Under the Securities Act (Regulation A), 80 Fed. Reg. 21,805, 21,856 (Apr. 20, 2015) (to be codified at 17 C.F.R. pt. 200, 230, 232, 239, 240, 249, 260).

⁷² Scott, *supra* note 13, at 383.

delay or avoid becoming reporting companies by increasing the threshold at which issuers are required to register under the Exchange Act.⁷³ “Prior to the passage of the JOBS Act, Section 12(g) of the Exchange Act required a company with more than \$10 million i[n] assets and more than five hundred shareholders of record to register a security with the SEC.”⁷⁴ Title V raises the shareholder of record threshold from five hundred persons to two thousand persons, or five hundred persons who are not accredited investors, and it excludes persons who received the securities under an employee compensation plan from the shareholder of record classification.⁷⁵ Title VI, in relevant part, further amends section 12(g) of the Exchange Act by raising the shareholder of record threshold for banks, bank holding companies, and savings and loan holding companies to two thousand persons.⁷⁶

C. Impact of the JOBS Act on the Biotech IPO Market

Over the six years since Congress passed the JOBS Act, small companies raising capital have widely adopted the Act’s provisions into standard practice. However, politicians, businesspeople, and attorneys still debate whether the Act’s requirements should be further relaxed or changed due to concerns about fraud.⁷⁷ Since Title I of the JOBS Act went into effect immediately after the Act’s passage, there have been mixed reviews as to whether the Act has actually been

⁷³ See *Changes to Exchange Act Registration Requirements to Implement Title V and Title VI of the JOBS Act*, 81 Fed. Reg. 28,689, 28,689–90 (May 10, 2016) (to be codified at 17 C.F.R. pt. 230, 240); *Changes to Exchange Act Registration Requirements to Implement Title V and Title VI of the JOBS Act*, U.S. SEC. & EXCHANGE COMMISSION (May 24, 2016), <https://www.sec.gov/info/smallbus/secg/jobs-act-section-12g-small-business-compliance-guide.htm> [<https://perma.cc/CJ47-5753>].

⁷⁴ Scott, *supra* note 13, at 384.

⁷⁵ *Id.* at 385; *Changes to Exchange Act Registration Requirements to Implement Title V and Title VI of the JOBS Act*, *supra* note 73.

⁷⁶ *Id.*; see also Scott, *supra* note 13, at 385.

⁷⁷ See Zanki, *supra* note 54.

successful in measurably increasing the number of IPOs.⁷⁸ In 2014, 275 companies went public, a fourteen-year high, and EGCs comprised eighty-five percent of IPOs from the Act's enactment through mid-2015.⁷⁹ The number of IPOs per year slowed through 2016 and increased slightly in 2017,⁸⁰ but EGCs remained a significant "proportion of companies pricing IPOs, demonstrating the lasting effect of the JOBS Act on the public market."⁸¹

Descriptive evidence of the companies going public around the enactment of the JOBS Act suggested that the biotech industry was largely responsible for the post-JOBS Act increase in IPOs.⁸² However, a study sampling IPO activity from January 2001 to March 2014 found that the primary

⁷⁸ *Id.* (attributing growth in IPO activity in part to market recovery since the recession); see also *Five Years Later: Did the Jobs Act Change the IPO Market (or Did the IPO Market Change the Jobs Act)?*, FIN. EXECUTIVES INT'L (Feb. 24, 2017), <https://www.financialexecutives.org/Research/News/2017/Five-Years-Later-Did-the-Jobs-Act-Change-the-IPO.aspx> [<https://perma.cc/XJ4T-Y8WP>] (suggesting that if a company was already planning to go public, passage of the Act was neither the trigger nor the but-for cause of the company going public). *But see* Michael J. Zeidel, *The JOBS Act: Did It Accomplish Its Goals?*, HARV. L. SCH. F. ON CORP. GOVERNANCE & FIN. REG. (July 18, 2016), <https://corpgov.law.harvard.edu/2016/07/18/the-jobs-act-did-it-accomplish-its-goals/> [<https://perma.cc/WK43-D32V>] ("EGCs taking advantage of the reduced regulatory requirements notably have contributed to an increase in the number of IPOs.").

⁷⁹ Zeidel, *supra* note 78. In 2013, a year after passage of the JOBS Act, the number of IPOs increased from 128 in 2012 to 222, and the proceeds from IPOs increased from \$43.9 billion to \$71.9 billion. In 2014, there were 275 IPOs accounting for \$90 billion in total proceeds, the high for each figure for the ten-year period from 2008 to 2017. *IPO Market Stats*, RENAISSANCE CAP. [hereinafter *IPO Market Stats*], <http://www.renaissancecapital.com/IPO-Center/Stats> [<https://perma.cc/92MC-DNCQ>].

⁸⁰ *IPO Market Stats*, *supra* note 79.

⁸¹ Zeidel, *supra* note 78.

⁸² Michael Dambra, Laura Casares Field & Matthew Gustafson, *The JOBS Act and IPO Volume: Evidence That Disclosure Costs Affect the IPO Decision*, 116 J. FIN. ECON. 121, 122 (2015); see also Zanki, *supra* note 54 (describing biotech as a "capital-hungry industry that often lacks product revenue and taps markets more frequently.").

drivers of IPO activity after enactment of the JOBS Act were the reduction in proprietary disclosure costs and improved market conditions across industries.⁸³ The study showed that favorable market trends in the biotech industry explained at least one-third of new biotech IPOs after enactment, whereas favorable market conditions in other industries could only account for ten percent of other industry IPOs.⁸⁴ Though the greatest increase in IPO market volume is concentrated in the biotech sector, the number of offerings across industries remains far below the level prior to 2001.⁸⁵

The biotech sector is particularly interesting because the value of a company is heavily impacted by the research cycle.⁸⁶ Along with capital formation, the financial performance and staying power of biotech companies are largely dependent on regulatory approval.⁸⁷ One of the value-maximizing strategies for biotech companies is to go public before being acquired by another company,⁸⁸ and regulatory approval can be a major factor in both the company's potential IPO and future M&A. While undergoing an IPO can act as a signal of a company's value,⁸⁹ it is not necessarily the case that the company will be a successful venture or that it has progressed along the research timeline or achieved any sort of regulatory approval. Furthermore, EGC is purely a securities law label, not an indication of a company being innovative or exciting or, of course, being supported by science.⁹⁰ In fact,

⁸³ Dambra et al., *supra* note 82, at 122.

⁸⁴ *Id.*

⁸⁵ *Id.*; see also Zanki, *supra* note 54.

⁸⁶ *The JOBS Act at Five: Examining Its Impact and Ensuring the Competitiveness of the U.S. Capital Markets: Hearing Before the H. Subcomm. on Capital Mkts., Sec. & Inv. of the H. Comm. on Fin. Servs.*, 115th Cong. 5 (2017) (statement of Andy Green, Managing Director, Economic Policy Center for American Progress) [hereinafter Statement of Green], <https://financialservices.house.gov/uploadedfiles/hhrg-115-ba16-wstate-agreen-20170322.pdf> [<https://perma.cc/U422-EP6D>].

⁸⁷ *See id.*

⁸⁸ *See id.*

⁸⁹ *See* Scott, *supra* note 13, at 368.

⁹⁰ Statement of Green, *supra* note 86, at 3.

another study found that, as of mid-2016, nearly half of EGC filers by assets were “real estate investment trusts, state and federally-chartered commercial and savings banks, and pharmaceutical preparations.”⁹¹

If the relaxed regulations set forth by the JOBS Act incentivize companies to undergo IPOs before they are ready, or because they are unable to find a purchaser in the acquisition market, the EGC could be of lower quality from an investment perspective.⁹² The same study analyzing EGCs as of mid-2016 found material weaknesses in management reports on internal controls in forty-six percent of active EGC filers.⁹³ Additionally, as the Theranos example illustrates, reporting issues are not the only potential problems facing investors. The company’s product quality, marketing, and overall management and strategy are all critical to an EGC’s survival and success. Concerns surrounding inferior biotech EGCs in the IPO market are magnified when analyzing the JOBS Act’s impact in the biotech crowdfunding market, where investors are both unaccredited and unsophisticated.

III. CROWDFUNDING RISK AND PROTECTIONS

A. Challenges for Biotech Crowdfunding

While the JOBS Act removed certain initial challenges to going public, the bulk of the Act outside of Title I reduced obstacles to raising private capital, thus allowing companies

⁹¹ *Id.* Note that this figure of percentage of EGC filers is lower when organized by revenue or number of filers.

⁹² *See id.* at 4.

⁹³ *Id.* A material weakness exists when some flaw within the company’s overall control system makes it at least reasonably possible for a material misstatement to be included in the company’s issued financial statements without being corrected. Kayla J. Gillan, Bd. Member, Pub. Co. Accounting Oversight Bd., Remarks at Spring Meeting of the Council of Institutional Investors: A Layperson’s Guide to Internal Control Over Financial Reporting (ICFR), (Mar. 31, 2006), https://pcaobus.org/News/Speech/Pages/03312006_GillanCouncilInstitutionalInvestors.aspx [<https://perma.cc/PZ7J-NLWK>].

to stay private and avoid IPOs for longer.⁹⁴ In contrast to the IPO reforms enacted under Title I of the JOBS Act, which took effect immediately, Title III was not implemented until May 2016.⁹⁵ The Crowdfunding provision is regarded as the most novel innovation of the Act, as small businesses tapped into an entirely new source of capital that permitted them to raise up to \$1 million annually in funding from unaccredited investors.⁹⁶

Financing in the biotech sector typically operates along a different timeline than in other startup areas commonly funded by venture capitalists, such as mobile applications or information technology.⁹⁷ Returns on investment are often delayed, causing investors to retain illiquid assets for a longer period of time, and initial investment is more likely to be higher and riskier.⁹⁸ The extensive time between development that encompasses years-long clinical trials and market entry for a new drug or medical device, along with the fact that fewer than one percent of new drugs make it to market, may deter venture capitalists from investing.⁹⁹ The challenge that early-stage technologies face when moving from academia to market has been termed the “Valley of Death,” as some believe that entrepreneurs need clinical data to attract venture capital funding but struggle to overcome the research and development capital requirements.¹⁰⁰ Others argue that the

⁹⁴ Zanki, *supra* note 54.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ Farnkoff, *supra* note 14, at 156.

⁹⁸ *Id.*

⁹⁹ *Id.* at 157.

¹⁰⁰ Deanna Pogorelc, *The Biotech Valley of Death Has Become the Uncrossable Canyon. Here's One Innovative Approach to Funding*, MEDCITY NEWS (Sept. 21, 2012, 10:42 AM), <https://medcitynews.com/2012/09/the-biotech-valley-of-death-has-become-the-uncrossable-canyon-heres-one-innovative-approach-to-funding/?rf=1> [<https://perma.cc/U3VW-YDJR>]; see also Meg Graham, *How iBio Helps Biotech Firms Through 'Valley of Death,'* CHI. TRIB. (Oct. 5, 2015, 5:30 AM), <https://www.chicagotribune.com/bluesky/originals/ct-warren-ribbley-ibio-bi-20151002-story.html> (on file with the *Columbia Business Law Review*); cf. Martin Zwilling, *10 Ways for*

“Valley of Death” is merely a representation of supply and demand—that early-stage biotech startups fail because there are too many of them or that their ideas or entrepreneurs are not good enough.¹⁰¹ Still others question whether the “Valley of Death” exists at all, as one study observed a greater proportion of Series A financings directed to biotech companies with drugs in the early stages of development compared to companies with drugs in later stages.¹⁰² Even if companies with early-stage drugs receive comparatively more funding to companies with later stage drugs, if there are more of the former, a perceived challenge to obtaining venture capital investment is possible.

Nevertheless, the Crowdfunding provision provides an alternative path for investment in biotech. Low-dollar investors, representing an assortment of interests, may be less concerned about the success of the company than a venture capital firm that assumes a large amount of downside risk for each investment.¹⁰³ In addition to being less risk averse, these low-dollar investors may be more attracted to the humanitarian goal of the EGC and more patient with the return on investment.¹⁰⁴ Crowdfunding issuers may include charitable foundations or individuals with personal stories and social media acumen that can inspire others to invest in

Startups to Survive the Valley of Death, FORBES (Feb. 18, 2013, 11:30 PM), <https://www.forbes.com/sites/martinzwilling/2013/02/18/10-ways-for-startups-to-survive-the-valley-of-death/#20ef08a869ef> [https://perma.cc/5J6J-AAMK] (describing the “Valley of Death” term as applied to startups generally).

¹⁰¹ Brandon Glenn, *In Biotech, the Popular Valley of Death Meme is Really Just Classic Supply and Demand*, MEDCITY NEWS (Feb. 24, 2012, 1:39 PM), <https://medcitynews.com/2012/02/in-biotech-the-popular-valley-of-death-meme-is-really-just-classic-supply-and-demand/> [https://perma.cc/SZ97-3YL7].

¹⁰² Bruce Booth, *Where Does All That Biotech Venture Capital Go?*, FORBES (Feb. 9, 2015, 10:21 AM), <https://www.forbes.com/sites/brucebooth/2015/02/09/where-does-all-that-biotech-venture-capital-go/#6deaa7de4676> [https://perma.cc/2FVB-BZPW].

¹⁰³ Farnkoff, *supra* note 14, at 157.

¹⁰⁴ *Id.* at 158–59.

a venture that could take a long time to pay off.¹⁰⁵ Spreading out the investment among investors with different incentives and perhaps less risk aversion to invest in biotech can help EGCs cross the “Valley of Death.”¹⁰⁶

While crowdfunding may offer a financing solution for biotech startups, many are concerned that even with low-dollar investments, unaccredited investors will be subject to heightened risk and losses resulting from fraud and self-dealing.¹⁰⁷ In the 1980s, small offering exemptions under Rule 504 resulted in widespread abuse through penny stock securities fraud.¹⁰⁸ Without federal mandatory disclosure or state registration requirements, bad actors issued up to \$1 million of securities in New York to favored groups.¹⁰⁹ The bad actor issuers then artificially drove up prices in the secondary market so that the favored initial investors could sell at a profit and new investors were left with inflated shares, leading to a substantial loss as the shares inevitably declined.¹¹⁰ Combining the internet and social media with the relaxed regulations and oversight could lead to scams at an even greater scale, as bad actors are provided with new opportunities to influence potential investors.¹¹¹ In the biotech sector specifically, investors’ risks are magnified as issuers promising cures of rare diseases “may attract a more vulnerable subset of unsophisticated investors who are more

¹⁰⁵ *Id.* at 159–60.

¹⁰⁶ *Id.*

¹⁰⁷ See Devin Thorpe, *Worries About Fraud Top List of Crowdfunding Concerns*, FORBES (Nov. 29, 2017, 9:46 PM), <https://www.forbes.com/sites/devinthorpe/2017/11/29/worries-about-fraud-top-list-of-crowdfunding-concerns/#7749d9ad48f0> [<https://perma.cc/B65S-6WYM>]; cf. Drew Prindle, *Don't Get Burned! How to Back Crowdfunding Projects the Smart Way*, DIGITAL TRENDS (Aug. 12, 2018, 8:14 AM), <https://www.digitaltrends.com/cool-tech/crowdfunding-tips-avoid-scams-kickstarter-indiegogo/> [<https://perma.cc/2LYE-LBUS>].

¹⁰⁸ Farnkoff, *supra* note 14, at 161.

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

willing to part with their money for a good cause.”¹¹² The unaccredited investor discovering the opportunity to invest in a biotech startup will not be able to conduct the rigorous due diligence that venture capital firms, and healthcare venture capital firms in particular, are trained to perform.

Typical venture capital firms and angel investors utilize a variety of tools to mitigate risks when investing in startups. Venture capital firms conduct staged financing through detailed investment contracts.¹¹³ Venture capitalists and angel investors may release money over time, and only when the startup achieves certain pre-set milestones.¹¹⁴ They screen startups in person, sometimes multiple times, and they either are or employ individuals with technical expertise in the field.¹¹⁵ The in-person contact not only weeds out low-quality ventures, but also creates a bond of trust that can encourage productive disclosure.¹¹⁶ Venture capital firms, in addition to engaging in staged financing, will “take preferred stock with liquidation preferences in exchange for their investments, which signals the entrepreneur’s belief that the startup will be worth more than these preferences.”¹¹⁷ Venture capitalists also frequently take board positions in the startup, and angel investors will similarly visit and engage with the startups they fund.¹¹⁸ By taking a corporate governance role either formally or informally post-investment, as well as by taking numerous measures to research and contract before making an investment, venture capital firms and angel investors are better able to reduce the agency costs that result from asymmetrical information and extreme levels of uncertainty during the initial stages of startup financing.¹¹⁹

¹¹² *Id.* at 162.

¹¹³ Ibrahim, *supra* note 14, at 574.

¹¹⁴ *Id.*

¹¹⁵ *See id.* at 575–76.

¹¹⁶ *See id.* at 576.

¹¹⁷ *Id.* at 574.

¹¹⁸ *Id.* at 575–76.

¹¹⁹ *Id.* at 574, 576.

Crowdfunding investors cannot employ the mixture of screens used by angel investors and venture capital firms prior to or during the investment period. Instead, crowdfunding investors may rely only on information directly available on the intermediary's platform or notices directing the investor to the funding portal or broker.¹²⁰ The JOBS Act prohibits the issuer from advertising "the terms of the offering, except for notices which direct investors to the funding portal or broker."¹²¹ Thus, any advertising made through a communication channel other than directly on the intermediary's platform must be limited to these notices, which can include no more than a statement that the issuer is conducting a crowdfunding offering, the name of the intermediary, a link directing the investor to the intermediary's platform, the terms of the offering (defined as the nature, price, and amount of the securities offered and the closing date of the offering period), and narrow factual information about the legal identity and business location of the issuer.¹²² The SEC's limitation on advertising was intended in part to protect investors by "directing them to the intermediary's platform where they can access the disclosures necessary for them to make informed investment decisions."¹²³

These disclosures, discussed *infra* Section IV.A, may be insufficient for crowdfunding investors in the biotech sector.¹²⁴ Instead of the product's scientific and technical information, which would be carefully reviewed by potential angel investors and venture capital firms, these mandatory crowdfunding disclosures focus primarily on the offering itself

¹²⁰ See Crowdfunding, 80 Fed. Reg. 71,387, 71,424–25 (May 16, 2015) (to be codified at 17 C.F.R. pt. 200, 227, 232, 239, 240, 249, 269, 274).

¹²¹ 15 U.S.C. § 77d-1(b)(2) (2012).

¹²² See Crowdfunding, 80 Fed. Reg. at 71,424–25; see also 17 C.F.R. § 227.204 (2015).

¹²³ See Crowdfunding, 80 Fed. Reg. at 71,425.

¹²⁴ See *infra* text accompanying notes 173–175; see also *supra* notes 61–64 and accompanying text.

and the financial condition of the issuer.¹²⁵ A crowdfunding issuer *can* “communicate other information that might occur in the ordinary course of its operations and that does not refer to the terms of the offering” without violating the advertising prohibition.¹²⁶ However, this permitted factual business information carries risks to biotech crowdfunding investors because it can also be incomplete, misleading, or even fraudulent.

B. Crowdfunding Investor Limits

To reduce the potential harms to investors, the Crowdfunding provision anticipated several protective measures aimed at keeping individual investment at low dollar amounts. The statute provides a “single-issuer investment limit,” a limit on how much investors can invest in a single venture, and an “aggregate investment limit” that requires intermediaries to ensure that investors do not exceed their limits among all ventures.¹²⁷ The single-issuer investment limit is defined as a proportion or maximum dollar amount of the investor’s annual income or net worth.¹²⁸ If any one investor exceeds this amount with any one issuer, the issuer loses its registration exemption.¹²⁹ On the other hand, the registration exemption is not conditioned on all investors staying within their *aggregate* investment limit; instead, the statute demands that the intermediary make efforts to ensure that investors do not exceed the aggregate investment limit.¹³⁰ Issuers who have accepted funding from investors who have exceeded their aggregate investment limit thus do not lose their exemption, as long as those investors’

¹²⁵ See *infra* text accompanying notes 173–175.

¹²⁶ See Crowdfunding, 80 Fed. Reg. at 71,425.

¹²⁷ Farnkoff, *supra* note 14, at 163.

¹²⁸ *Id.* at 165.

¹²⁹ *Id.* at 166.

¹³⁰ *Id.*

intermediaries have taken steps, undefined in the statute, to prevent the investors from exceeding their limits.¹³¹

Because intermediaries may be brokers or merely online funding portals,¹³² the current measures they can use to ensure an investor's compliance with either the single-issuer or aggregate investment limits are based on the investor's own representations.¹³³ Where the intermediary otherwise complies with the statute—including ensuring that the investor confirms understanding of the educational information required by the SEC and answers questions demonstrating that he or she understands the level of risk and illiquidity generally applicable to investments in startups and small issuers—the intermediary has a reasonable basis for believing that the investor satisfies the investor limitations.¹³⁴ Unless the issuer otherwise knows that the investor is unqualified to make the investment, the issuer and intermediary are both protected from liability, and the issuer can retain its exemption.¹³⁵

The SEC found this self-verification standard satisfactory because of the hardship intermediaries would face by monitoring and independently verifying whether investors would stay within their investment limits.¹³⁶ However, this

¹³¹ *Id.*

¹³² *Regulation Crowdfunding: A Small Entity Compliance Guide for Crowdfunding Intermediaries*, U.S. SEC. & EXCHANGE COMMISSION [hereinafter *Regulation Crowdfunding*], <https://www.sec.gov/divisions/marketreg/tmcompliance/cfintermediaryguide.htm> [<https://perma.cc/T6RD-75QD>] (last modified May 13, 2016).

¹³³ Farnkoff, *supra* note 14, at 167.

¹³⁴ *Id.* at 168; *see also Regulation Crowdfunding*, *supra* note 132.

¹³⁵ Farnkoff, *supra* note 14, at 168. The issuer will lose “the crowdfunding exemption for the entire equity or debt offering in the event that an intermediary fails to adequately ensure that a lone investor stays within his aggregate investment limit.” *Id.* at 176. The intermediary is responsible for tracking the investments an investor makes with that same intermediary to ensure the investor does not exceed its limits, but the intermediary is not responsible for tracking the investor's investments outside of the intermediary's own systems. *Id.*

¹³⁶ *Id.* at 168.

hands-off approach to compliance shifts risk away from intermediaries and issuers, and it relies on unaccredited and unsophisticated investors to protect their own interests.¹³⁷ Optimistic crowdfunding investors may attempt to maximize their investment and thus their hopeful return by misrepresenting their net worth, annual income, or aggregate crowdfunding investment levels.¹³⁸ While the JOBS Act legislators may have intended to tap into this optimism to help solve financing problems for startups, they left the door open to overinvestment and to the subsequent risk of overexposure to bad actors.

As the statute stands now, if the intermediary finds that an investor has reached his or her aggregate investment cap and prevents the investor from further investing, the investor could theoretically open an account at another intermediary and invest his or her entire cap amount there. There are plenty of intermediaries an investor can choose from—as of November 1, 2018, there were forty-seven funding portals and hundreds of broker-dealers who are members of the Financial Industry Regulatory Authority, registered with the SEC, and allowed to engage in crowdfunding as intermediaries.¹³⁹ The second intermediary would be bound by the same diligence requirements, but as noted above, the investigation standard is not high as long as the intermediary has a reasonable basis to believe the investor is being truthful.

To address this issue, the SEC could create and operate a system containing verifiable proof of investor income, net worth, and investments with crowdfunding intermediaries.¹⁴⁰ In the payday lending area, for example, some states require lenders to check a centralized database, containing records of all lending, in order to keep people from exceeding aggregate

¹³⁷ *See id.* at 171.

¹³⁸ *Id.* at 175.

¹³⁹ *Funding Portals We Regulate*, FIN. INDUS. REG. AUTH. (Nov. 1, 2018), <https://www.finra.org/about/funding-portals-we-regulate> [<https://perma.cc/L9GR-FV6D>].

¹⁴⁰ Farnkoff, *supra* note 14, at 177–78.

borrowing limits by shifting lenders.¹⁴¹ Creating a similar crowdfunding database could be cost-prohibitive, though, and may raise privacy concerns that may trouble investors. The SEC has explored, but thus far rejected, the idea.¹⁴²

While a centralized system operated by the government could be expensive, with costs borne by taxpayers and investors alike, the creation of third-party verification systems in the private sector could potentially reduce costs, both to the public and overall.¹⁴³ Private third parties could compete for the business of intermediaries, but the competitors would still need to share specific investment information, such as which investors are working with which intermediaries and how much each person is investing.¹⁴⁴ If the third parties were to request self-verification information from the investors (as intermediaries do now), the same problems facing intermediaries would be transferred to the third parties. Furthermore, in informationally asymmetric markets, a monopoly is likely to arise, thus not actually reducing the costs associated with a federally controlled system.¹⁴⁵

Though crowdfunding may not currently be able to take advantage of these other corporate law-based solutions for investor protection, biotech crowdfunding can tap into additional sources of legal protection. FDA approval requirements and patent law greatly influence and attempt to guard interests of both biotech consumers and companies. By

¹⁴¹ See, e.g., Kim Chandler, *Supreme Court Upholds Payday Loan Database*, WASH. TIMES (Apr. 27, 2015), <https://www.washingtontimes.com/news/2015/apr/27/supreme-court-upholds-payday-loan-database/> [https://perma.cc/LMB4-Y4QU]; Riley Snyder, *Audit Finds Nearly a Third of Nevada Payday Lenders Violated Rules over Last Five Years*, SPARKS TRIB. (May 9, 2018), <https://sparkstrib.com/2018/05/09/audit-finds-nearly-a-third-of-nevada-payday-lenders-violated-rules-over-last-five-years/> [https://perma.cc/UWF5-UJD4].

¹⁴² Farnkoff, *supra* note 14, at 179.

¹⁴³ *Id.* at 180.

¹⁴⁴ *Id.*

¹⁴⁵ See *id.*

including disclosure relating to these two areas within the current disclosure requirements under Title III, crowdfunding investors can become better informed of the nature of the investment and better protected against bad actor issuers.

C. Liability of Issuers and Intermediaries

Though not a preventative protection, investors have a private cause of action against an issuer for consideration or damages if the issuer makes a misleading statement of material fact, by either making an untrue statement or omitting a material fact.¹⁴⁶ But due to restrictions on individual investment amounts, most crowdfunding plaintiffs may not have a strong incentive to sue on their own, instead likely relying on class action suits against potentially fraudulent issuers.¹⁴⁷

Section 302 of the JOBS Act creates liability for issuers analogous to section 12(a)(2) of the Securities Act, with section 12(b), loss causation, and section 13, statute of limitations, of the Securities Act attaching to liability as well.¹⁴⁸ Issuers can avoid liability under section 12(a)(2) if they can prove they did not know, and in the exercise of reasonable care could not have known, of the material misrepresentation or omission.¹⁴⁹ Additional defenses include that the investor knew of the misinformation¹⁵⁰ or that it did not cause depreciation in the value of the security.¹⁵¹ Investors also have a cause of action under section 10 of the Exchange Act for a violation of Rule 10b-5, but, among other elements, the investor must prove scienter.¹⁵²

¹⁴⁶ *Id.* at 170; *see also* 15 U.S.C. § 77d-1.

¹⁴⁷ Sherief Morsy, Note, *The JOBS Act and Crowdfunding: How Narrowing the Secondary Market Handicaps Fraud Plaintiffs*, 79 BROOK. L. REV. 1373, 1385 (2014).

¹⁴⁸ Securities Act of 1933, 15 U.S.C. §§ 77l–77m (2012); 15 U.S.C. § 77d-1 (2012).

¹⁴⁹ *See* Morsy, *supra* note 147, at 1386.

¹⁵⁰ 17 C.F.R. § 230.159 (2005).

¹⁵¹ *See* Morsy, *supra* note 147, at 1386.

¹⁵² *Id.* at 1387–88.

Identifying the issuer in a crowdfunding offering for the purposes of liability presents an additional challenge. Because entrepreneurs engaged in crowdfunding are by definition small companies, they may not have the resources to defend against a class action lawsuit. The companies may only consist of one or a few people, who use the funds raised immediately to cover operating costs or research and development. The statute defines issuers as:

[A]ny person who is a director or partner of the issuer, and the principal executive officer or officers, principal financial officer, and controller or principal accounting officer of the issuer (and any person occupying a similar status or performing a similar function) that offers or sells a security in a transaction exempted by the provisions of section 4(6), and any person who offers or sells the security in such offering.¹⁵³

Under this definition, the SEC believes that an intermediary, including a funding portal, could be considered an issuer for the purposes of liability.¹⁵⁴ The investor would have a cause of action against the intermediary if the startup made materially false statements and the intermediary merely passed them along in the offering to the investor.¹⁵⁵ The SEC suggests that if the original issuer—the startup—was available, the intermediary would not be jointly liable. Rather, the investor could bring action against the intermediary only if the original issuer was judgment-proof—for example, if the original issuer disappeared with the investor's money after making materially false statements.¹⁵⁶ However, the SEC still does retain the reasonable belief standard for liability, such that an intermediary would only be subject to liability for a materially false statement propagated through the intermediary if the intermediary

¹⁵³ Jumpstart Our Business Startups Act, Pub. L. No. 112-106, § 302, 126 Stat. 306, 319 (2012) (codified as amended in scattered sections of 15 U.S.C.).

¹⁵⁴ Farnkoff, *supra* note 14, at 170.

¹⁵⁵ *See id.*

¹⁵⁶ *See id.*

failed to conduct an adequate review of the original issuer's statements.¹⁵⁷

The statute is also vague as to what constitutes reasonable or sufficient review by the intermediary as to the issuer's statements and background. The Crowdfunding provision, in addition to requiring the intermediary to ensure that investors do not breach their single-issuer or aggregate investment limits, requires the intermediary to "take measures to reduce the risk of fraud, including background and securities enforcement regulatory checks on the officers, directors and 20% shareholders of each issuer whose securities it offers and any other requirements the SEC adopts."¹⁵⁸ The timing and substantiality of the background and regulatory history checks on the issuer are not described in the statute. The intermediary may only be required to conduct one background check before listing the issuer on the funding portal.¹⁵⁹

In any startup, the entrepreneur knows more than potential investors, who typically have no prior background knowledge of the entrepreneur to consider. Furthermore, the entrepreneur has an incentive to portray the venture as new and revolutionary, or at least as an improvement on existing options, in order to attract financing. The Theranos scandal is a prime example of how information asymmetry and market uncertainty can be greatly exacerbated when the entrepreneur takes active steps to obscure her technology—pitching empty promises to revolutionize the medical field—and investors are unsophisticated in the technological area. Though secrecy and hype are not unique in a startup's early days,¹⁶⁰ the dangers can be too great to rely on liability as a

¹⁵⁷ See *id.*

¹⁵⁸ *JOBS Act: Crowdfunding Summary*, PRACTICAL L. CORP. & SEC., Oct. 23, 2013, Practical Law Practice Note 6-518-7396.

¹⁵⁹ Ibrahim, *supra* note 14, at 605.

¹⁶⁰ See Issie Lapowsky, *Theranos' Scandal Exposes the Problem with Tech's Hype Cycle*, WIRED (Oct. 15, 2015, 3:33 PM), <https://www.wired.com/2015/10/theranos-scandal-exposes-the-problem-with-techs-hype-cycle/> [<https://perma.cc/7HZP-2C4A>] ("grandiose promises

deterrent for issuers or solution for investors. Especially in the biotech sector, which directly implicates individuals' medical treatment,¹⁶¹ the legal framework should take affirmative steps to prevent harm to investors and consumers alike.

IV. SUPPLEMENTARY SOURCES OF INVESTOR PROTECTION FROM PATENT AND ADMINISTRATIVE LAW

A. Mandatory Disclosure Under Title III

Scholars have debated whether investor protection should be the central goal of securities regulation.¹⁶² Some argue that the objective of securities law should be the maximization of social welfare and that the best way to achieve that objective is through regulations aimed at encouraging investment by sophisticated institutional investors.¹⁶³ Discouraging individual investing has the potential to decrease the costs borne by issuers and the regulatory bodies that enforce compliance with the securities laws.¹⁶⁴ However, others argue that individual investing, regardless of the sophistication of investors, can produce efficiency benefits by providing an important source of liquidity.¹⁶⁵ Despite the academic debate

are table stakes in the tech industry, a requirement for luring both investors and early users. And typically, they're harmless.”)

¹⁶¹ *See id.* (comparing the fallout from Holmes's actions to promises made by executives at Facebook, Uber, and Tinder that their products would become global networks at the early stages of financing).

¹⁶² *See* Colleen Honigsberg, Robert J. Jackson, Jr. & Yu-Ting Forester Wong, *Mandatory Disclosure and Individual Investors: Evidence from the JOBS Act*, 93 WASH. U. L. REV. 293, 299–300 (2015) (describing several perspectives on whether the securities laws should encourage individual investor participation).

¹⁶³ *Id.* at 299 (citing Zohar Goshen & Gideon Parchomovsky, *The Essential Role of Securities Regulation*, 55 DUKE L.J. 711 (2006)).

¹⁶⁴ *Id.* (citing Luigi Zingales, *The Future of Securities Regulation*, 47 J. ACCT. RES. 391, 417 (2009)).

¹⁶⁵ *Id.* (citing Ron Kaniel et al., *Individual Investor Trading and Stock Returns*, 63 J. FIN. 273, 274 (2008); Qin Wang & Jun Zhang, *Individual*

over what the securities laws should aspire to achieve, policymakers have consistently focused on individual investor protection as a principal regulatory objective.¹⁶⁶

In order to protect and provide individual investors with equal access to securities markets, mandatory disclosure rules have become the cornerstone of federal securities law.¹⁶⁷ Whether mandatory disclosure actually achieves these goals of protection and access for individual investors is another point of academic debate—one side argues that disclosure facilitates individual investor participation by reducing information asymmetry among different types of investors, while the other suggests that additional disclosure does not benefit individual investors, who are already overloaded with information and unable to extract relevant information from complex securities filings.¹⁶⁸ A study collecting and analyzing empirical evidence around the IPO stage demonstrated that “reducing the information that firms are required to disclose before an IPO leads to a statistically and economically significant decrease in individual investor participation in the IPO. Importantly, however, this effect is substantially reduced during the week of trading following the IPO—and disappears completely after two weeks.”¹⁶⁹ The authors found that “individual investors who are at an informational disadvantage to other investors will be less likely to participate in securities markets.”¹⁷⁰ Mandating disclosure

Investor Trading and Stock Liquidity, 45 REV. QUANTITATIVE FIN. & ACCT. 485, 486 (2015)).

¹⁶⁶ *Id.* at 300.

¹⁶⁷ *Id.* at 295.

¹⁶⁸ *Id.* (citing, for example, Brian J. Bushee et al., *Open Versus Closed Conference Calls: The Determinants and Effects of Broadening Access to Disclosure*, 34 J. ACCT. & ECON. 149 (2003); Alastair Lawrence, *Individual Investors and Financial Disclosure*, 56 J. ACCT. & ECON. 130 (2013); Brian P. Miller, *The Effects of Reporting Complexity on Small and Large Investor Trading*, 85 ACCT. REV. 2107 (2010)).

¹⁶⁹ *Id.* at 296.

¹⁷⁰ *Id.* at 296.

can address this disadvantage but is “not the only mechanism available to address these information asymmetries.”¹⁷¹

As described *supra* Section III.B, the Crowdfunding provision primarily focuses on investor protection by requiring the intermediary to ensure the investor does not invest beyond his or her means.¹⁷² The burden is placed on the intermediary not only to verify the investor’s activity, but also to ensure that the issuer is credible. In contrast to intermediary enforcement, increasing issuer transparency and disclosure is another option to protect crowdfunding investors. Section 302 of the JOBS Act mandates certain issuer disclosures, but the disclosures are mainly descriptive of the issuer’s current financial condition and intended uses for the funds to be raised.¹⁷³ Ownership and capital structure disclosures describe the securities themselves, their valuation, and the risks to “purchasers of the securities relating to minority ownership in the issuer and future corporate actions, including additional share issuances, a sale of the issuer or transactions with related parties.”¹⁷⁴

Missing from the disclosure requirements, however, are any details of the actual achievements and potential success of the venture. Because this kind of information might occur in the ordinary course of business, entrepreneurs can communicate it with the public through social media or other means outside of the intermediary’s platform, without violating the advertising prohibition, so long as the communication does not refer to the terms of the offering.¹⁷⁵ While entrepreneurs may be incentivized to disclose this information in order to attract funding, fear of competitors appropriating any disclosures could nonetheless drive entrepreneurs to stay silent. Startups, often not advised by

¹⁷¹ *Id.* at 297.

¹⁷² *See supra* text accompanying notes 127–138.

¹⁷³ Jumpstart Our Business Startups Act, Pub. L. No. 112-106, § 302, 126 Stat. 306, 315–21 (2012) (codified as amended in scattered sections of 15 U.S.C.); *see also supra* notes 61–64 and accompanying text.

¹⁷⁴ *JOBS Act: Crowdfunding Summary, supra* note 158.

¹⁷⁵ *See* Crowdfunding, 80 Fed. Reg. 71, 387, 71,424–25 (May 16, 2015) (to be codified at 17 C.F.R. pt. 200, 227, 232, 239, 240, 249, 269, 274).

legal counsel, may also withhold this information for fear of liability attaching when disclosing certain positive or forward-looking information without appropriately disclosing the associated risks. Lastly, instances of issuer fraud, such as Theranos, show that veils of secrecy and public hype are enough to draw substantial funding without open and honest disclosure.

This Note proposes that biotech crowdfunding, with its unique challenges of obtaining investment alongside regulatory approval and heightened information asymmetry, utilize other areas of the law outside of securities law to better protect investors. Mandating disclosure of FDA and patent milestones on the intermediary's platform can provide easily understandable and accessible information to unsophisticated investors and help them make more informed decisions prior to investment. By hosting this information on the intermediary's platform, all issuer disclosures are provided in a centralized location viewable to anyone seeking to invest in the offering. Further, limiting disclosure to checkboxes and brief explanations and disclaimers noting whether milestones were achieved can reduce the potential for disclosure overload as well as misleading hype.

B. Disclosure Requirements Relating to FDA Approvals

The success of biotech ventures is distinctive compared to companies in other industries, as it not only depends on market interest and uptake, but is also highly contingent on regulatory approval. While the need for approval can serve as the main reason why many ventures fail, regulations not only protect the public from harmful or inaccurate products, but also signal to potential investors the quality and probability of commercial success. Developers of both medical drugs and devices must reach clear goalposts before their products can reach consumers, and they can and should disclose their

progress along the way.¹⁷⁶ This Subsection provides an overview of the many FDA regulations that a biotech startup must surmount, the prospects and success of which should be disclosed to potential investors through the intermediary broker or funding portal.

The FDA is the primary regulatory authority for both medical drugs and devices, and it sets out milestones governing development from pure laboratory research to consumers' hands.¹⁷⁷ For medical drugs, FDA review begins

¹⁷⁶ Though outside the scope of this Note, it is important to recognize that the regulatory framework governing companies that manufacture diagnostic tests (such as Theranos) is distinguishable from the regulatory framework governing biotech startups that produce drugs and devices. Diagnostics companies can avoid submitting their product to the FDA before bringing the test to market through a regulatory loophole for laboratory developed tests ("LDTs"). See Arielle Duhaime-Ross, *Theranos Isn't the Only Diagnostics Company Exploiting Regulatory Loopholes*, VERGE (Nov. 11, 2015, 8:28 AM) <https://www.theverge.com/science/2015/11/11/9706356/fda-theranos-health-diagnostics-cancer-tests-regulation-loophole-ldt> [<https://perma.cc/F7U3-D84H>]; see also *Laboratory Developed Tests*, U.S. FOOD & DRUG ADMIN. (Oct. 12, 2018), <https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/laboratorydevelopedtests/default.htm> [<https://perma.cc/MU6T-42GG>]. This loophole allows any company that develops and conducts a diagnostic test in its own laboratory to use the test on real patients without having to first submit to the FDA. See *id.* While the Centers for Medicare and Medicaid Services ("CMS") regulates laboratories and the quality of laboratory testing, it does not review tests for safety and effectiveness of patient treatment and diagnosis, as that falls under the FDA's purview. *Clinical Laboratory Improvement Amendments (CLIA)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 19, 2018), <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=CLIA> [<https://perma.cc/YS69-8TKC>]; *CLIA Overview...*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 22, 2013), https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/LDT-and-CLIA_FAQs.pdf [<https://perma.cc/T9MC-X79E>]. Arguments for closing this loophole, as well as improving the relationship between the FDA and CMS as related to oversight of laboratory testing and diagnostic devices, are especially of interest in the wake of the Theranos scandal, but this Note is limited to considering the FDA regulation of medical drugs and devices only.

¹⁷⁷ *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/>

once the researchers have submitted an investigational new drug application (“IND”).¹⁷⁸ The IND must demonstrate that the drug is ready for human testing by showing the results of preclinical animal testing and proposing trial protocols for human testing.¹⁷⁹ Both the FDA and a local institutional review board, a panel composed of scientists and non-scientists in hospitals and research institutions who oversee clinical research procedures and ethics, must approve the IND before clinical testing in humans can begin.¹⁸⁰ Submission of the IND should be the first qualification a biotech developing a drug should disclose to potential investors.

Once the IND is approved, the three phases of clinical studies can begin.¹⁸¹ In Phase I, researchers test the drug in healthy volunteers to determine the drug’s side effects and how it is metabolized and excreted.¹⁸² Phase II studies can only begin if the researchers determine in Phase I that the drug is safe.¹⁸³ Phase II analyzes the effectiveness of the drug in treating people with a certain disease or condition, while researchers still monitor the safety of the drug in both the control and experimental groups.¹⁸⁴ If the trials continue to show that the drug is safe, as well as effective in Phase II, the FDA and the company or institution responsible for the drug meet to determine how Phase III large-scale trials should be conducted.¹⁸⁵ Phase III trials test different dosages of the drug on different populations, in combination with other drugs, in at least several hundred and up to several thousand individuals.¹⁸⁶ A biotech company should have to disclose to

ResourcesForYou/Consumers/ucm143534.htm [https://perma.cc/BS22-PV7V] (last updated Nov. 24, 2017).

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

potential investors (through the intermediary) which clinical phase its drug is in, as well as provide updates to current investors through annual reports of operations and financial statements, as already required by Title III.

If the drug successfully makes it through the three phases of clinical testing, the company or institution responsible for the drug must then submit a formal new drug application (“NDA”).¹⁸⁷ The NDA includes “all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured.”¹⁸⁸ After the FDA receives the NDA, the FDA has sixty days to decide whether to file the application for review or reject it for being incomplete.¹⁸⁹ The FDA’s expected timeline for reviewing and acting on NDAs is between six and ten months after the applications are received, depending on if the drug is classified as a standard or priority drug.¹⁹⁰ Even after approval, the FDA conducts “postmarket requirement and commitment studies to gather additional information about a product’s safety, efficacy, or optimal use.”¹⁹¹ The submission and pending status of the NDA are both incredibly useful indicators of the likelihood that a product will make it to market, and thus they should be disclosed to potential and current investors through the intermediary and annual updates.

The regulatory burden to get a drug to market is cumbersome and lengthy, with each clinical phase potentially lasting several years,¹⁹² but the path to approval is clear and well-known. Even among those not in the industry, people at least recognize the value of FDA approval and have some knowledge of clinical trial phases as indications of safety and effectiveness. As such, presentation of these signals is useful for individuals searching for a biotech company in which to invest, and it can help them differentiate between a variety of

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² *Id.*

companies engaged in crowdfunding aimed at remedying an illness or disease. Mandatory disclosure of FDA regulatory status makes clear which startups are not seeking FDA approval, either because they will not have the clinical data to support the safety and effectiveness of the drug or because the product does not actually qualify as a drug (and may therefore be exempt). In such cases, the startup can nonetheless provide its reason for not submitting the IND, the first stage of FDA regulatory approval. Disclosure could occur through a checklist on the funding portal, listing the regulatory stages in checkboxes with additional spaces provided for status updates or explanation. The disclosure should also include descriptions and disclaimers about what each stage means and its general probative value to the investment.

While the preceding discussion outlined the steps for regulatory approval of a medical drug, the FDA also regulates medical devices according to three regulatory classes—Classes I, II, and III—determined by the devices’ “intended use and the degree of risk they pose to the public.”¹⁹³ All manufacturers and initial distributors of medical devices must register their place of business with the FDA, and most are “required to list the devices that are made there and the activities that are performed on those devices.”¹⁹⁴ In addition to registering the business and listing the device, manufacturers of Class III devices must obtain premarket approval (“PMA”), the FDA’s scientific and regulatory review process evaluating safety and effectiveness of devices that support or sustain human life, prevent impairment of human health, or present possible unreasonable risk of illness or injury.¹⁹⁵ PMA is the most stringent regulatory requirement

¹⁹³ Sarah Y. Kwon, Note, *Regulating Personalized Medicine*, 31 BERKELEY TECH. L.J. 931, 937 (2016).

¹⁹⁴ *Device Registration and Listing*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm> [<https://perma.cc/MA3D-D8F7>] (last updated Sept. 27, 2018).

¹⁹⁵ *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>

for medical devices,¹⁹⁶ and it involves both analytical and clinical validation—ensuring that the laboratory test can accurately identify a sample (analytical validation) and can correctly link the sample to a specific disease or clinical action (clinical validation).¹⁹⁷ Regulations provide 180 days for the FDA to make a determination, though in practice the review process may take longer.¹⁹⁸ The review process can include a public meeting with an FDA advisory committee providing recommendations, and after the FDA notifies the applicant of its decision, a notice is published on the internet announcing the data underlying the decision and the process by which interested persons can petition for reconsideration.¹⁹⁹

FDA review of the PMA is required before Class III devices may be marketed, but other regulatory mechanisms are still in place for less risky medical devices.²⁰⁰ Those who desire to market other medical devices intended for human use—Class I, II, or III devices exempted from PMA—must submit a premarket notification 510(k) to the FDA.²⁰¹ The 510(k) submission must demonstrate that the device is substantially equivalent to—at least as safe and effective as—a legally marketed device, and before the device can be marketed, the FDA must find it to be so and provide an order clearing the device for commercial distribution.²⁰² The PMA and 510(k) measures are protections for consumers that can be utilized for investor protection as well, if made readily available

HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm [https://perma.cc/NRF3-2DUQ] (last updated Sept. 27, 2018).

¹⁹⁶ *Id.*

¹⁹⁷ Kwon, *supra* note 193, at 938.

¹⁹⁸ *Premarket Approval (PMA)*, *supra* note 195.

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> [https://perma.cc/TL2B-UGHW] (last updated Sept. 27, 2018).

²⁰² *Id.*

through the investment platform through a similar checkbox with explanation format.

For example, when first launched in 2007, the DNA testing-by-mail service 23andMe was lauded in the biotech sector—receiving a similar initial reaction as Theranos—as a transformative technology that allowed individuals to obtain a complete DNA report of health, hereditary traits, and ancestry.²⁰³ But in 2013, the FDA imposed a moratorium on marketing the test by constraining it as a diagnostic device subject to the Class III stringent PMA validation standards.²⁰⁴ The FDA warning and restriction on 23andMe’s marketing (which would extend until it had undergone the necessary approvals) proved to be surmountable, though, as 23andMe has since undergone another round of funding upon receiving approval.²⁰⁵ The FDA lifted the moratorium in April 2017, after reviewing data “through the *de novo* premarket review pathway, a regulatory pathway for novel, low-to-moderate-risk devices that are not substantially equivalent to an already legally marketed device.”²⁰⁶ “The decision is expected to open the floodgates for more direct-to-consumer

²⁰³ See, e.g., Larry Downes & Paul Nunes, *Regulating 23andMe Won’t Stop the New Age of Genetic Testing*, WIRED (Jan. 1, 2014, 6:30 AM), <https://www.wired.com/2014/01/the-fda-may-win-the-battle-this-holiday-season-but-23andme-will-win-the-war/> [<https://perma.cc/7E9D-EF62>].

²⁰⁴ Julia Belluz, *In an Amazing Turnaround, 23andMe Wins FDA Approval for Its Genetic Tests*, VOX (Apr. 6, 2017, 1:19 PM), <https://www.vox.com/2017/4/6/15207604/23andme-wins-fda-approval-for-its-genetic-tests> [<https://perma.cc/8RPQ-YKSQ>]; Downes & Nunes, *supra* note 203; Gina Kolata, *F.D.A. Will Allow 23andMe to Sell Genetic Tests for Disease Risk to Consumers*, N.Y. TIMES (Apr. 6, 2017), <https://www.nytimes.com/2017/04/06/health/fda-genetic-tests-23andme.html> [<https://perma.cc/BV2L-JU9R>]; see also Lapowsky, *supra* note 160.

²⁰⁵ Lapowsky, *supra* note 160.

²⁰⁶ Press Release, U.S. Food & Drug Admin., FDA Allows Marketing of First Direct-to-Consumer Tests that Provide Genetic Risk Information for Certain Conditions (Apr. 6, 2017) [hereinafter FDA Allows Marketing of First Direct-to-Consumer Tests], <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm551185.htm> [<https://perma.cc/5YNY-37H7>].

tests for disease risks, drawing a road map for other companies to do the same thing.”²⁰⁷ Additional tests based on the same technology submitted by 23andMe or other manufacturers will not have to undergo the same review, but instead will qualify for the less rigorous 510(k) premarket notification requirement.²⁰⁸ While regulatory approval can halt marketing, worthwhile companies will ultimately be able to surmount the capital and timing barriers, supported by investors who know that the company is intending to achieve, rather than avoid, FDA approval.

C. Patent Disclosure in Crowdfunding

Patent law also has a particularly pronounced effect on biotech over other types of technology. In electronics and software, the value of patent protection may be minimal given that innovation and the development timeline to get a product to market are so fast-paced that patents are easily circumvented. However, a patent is crucial to the commercial success of a biotech company, where developing and launching a product is much more time and resource intensive due in part to the research cycle and need for regulatory approval. Obtaining a patent on a medical drug or device provides a monopoly for a defined market sector—or specific disease indication—for a limited period of time and can lead to enormous profits. One of the primary goals of the patent system, in providing this monopoly, is the dissemination of technical information—allowing skilled artisans to innovate and learn from knowledge of the technical details of the invention.

A patent can also be used to advertise and promote useful embodiments of the invention to those not skilled in the art, such as investors,²⁰⁹ whether through disclosure of

²⁰⁷ Kolata, *supra* note 204.

²⁰⁸ FDA Allows Marketing of First Direct-to-Consumer Tests, *supra* note 206.

²⁰⁹ J. Jonas Anderson, *Nontechnical Disclosure*, 69 VAND. L. REV. 1573, 1574–75 (2016).

nontechnical information within the patent itself or simply through notifying individuals that a patent is pending or has been issued.²¹⁰ While these forms of nontechnical information do not meet patent law’s statutory written description and enablement requirements,²¹¹ they “can be highly useful and valuable to individuals seeking information about the technology,” signaling to other innovators, consumers, and investors the potential value of the inventive idea.²¹² A venture capitalist, for example, may not understand all the science behind a company’s portfolio of biotech inventions, but whether these products are patented can inform the investor’s decision and help to estimate the company’s value and future market share.²¹³ As such, entrepreneurs seeking crowdfunding should be required to disclose if a patent application will be filed—and if so, its application status—to potential investors through the intermediary broker or funding portal.

Unlike disclosure of a product’s status within the FDA’s regulatory approval process, though, disclosure of patent nontechnical information may be more likely to mislead investors because the (potential) existence of a patent can mistakenly convince unsophisticated individuals that the product is innovative, when the patent may actually be invalid or the invention technically useless.²¹⁴ Furthermore, many inventions may not qualify for patent protection, for reasons entirely unrelated to whether or not the company would be a good investment. For the same reasons that nontechnical disclosure can be valuable for investors, it can also present

²¹⁰ *Id.* at 1591 (“Indeed, nontechnical disclosure is more about the existence of a patent than what the patented invention covers.”).

²¹¹ A valid patent must “contain a written description of the invention” and “the manner and process of making it and using it” so that “any person skilled in the art. . . [can] make and use” the invention. 35 U.S.C. § 112(a) (2012).

²¹² Anderson, *supra* note 209, at 1575.

²¹³ *Id.* at 1591.

²¹⁴ *Id.* at 1576.

great risk, especially in crowdfunding, as it is aimed at persons unskilled both in the technical art and in investing.²¹⁵

In order to avoid vague or misleading information, the proposed disclosure requirements should provide checkboxes as to whether a patent has been filed and issued, with disclaimers as to reasons why a patent may not be filed as well as the probative value of patents generally on commercial success. Nontechnical disclosure that a patent exists provides another data point that the investor can use in deciding whether or not to invest in a company. This could potentially incentivize the investor to research more about the product's technical specifications while reducing the risk of material misinformation. As a backstop, Title III provides investors with a cause of action against a company that makes a misleading statement of material fact,²¹⁶ which investors can utilize when an entrepreneur misuses nontechnical patent disclosure.

V. CONCLUSION

The JOBS Act, likely in conjunction with other market factors, has seemingly invigorated the biotech investment market. While the enactment of Title III in May 2016 has raised concerns about investor protection across industries, biotech crowdfunding presents unique challenges to issuers, intermediaries, and investors. This Note has presented a wide-ranging description of the various protections available to potential biotech investors from bad actors, focusing on the crowdfunding protections currently set out in Title III and those provided by the FDA's regulatory authority and patent law. However, unless information as to a product's safety, effectiveness, and patentability is properly and timely disclosed, unsophisticated investors will likely not be able to distinguish good biotech investments from bad ones and could be convinced to overinvest due to potentially unmerited optimism in the venture.

²¹⁵ *See id.* at 1577.

²¹⁶ Farnkoff, *supra* note 14, at 170.

This Note proposes that biotech startups seeking crowdfunding should be required to disclose if they are seeking regulatory approval and where they are in the FDA approval process. If they are not seeking FDA approval, they should be required to disclose why they have chosen not to seek it. Similarly, the startup should be required to disclose whether a patent has been filed or issued. With more expansive disclosure requirements, investors will be better able to screen and make informed decisions as to the quality of the venture in which they are considering investing. Disclosure through the intermediary and a checkbox with explanation format can minimize the risk of disclosure overload for the unsophisticated investor. In biotech, FDA regulations and patent law already serve to protect consumers and innovators. By integrating these areas into the JOBS Act, they can help protect investors as well.