

SCIENTIFIC ADVISORY BOARDS: THE FORGOTTEN SHIELD

William J. Baker*

ABSTRACT

The Scientific Advisory Board (SAB) is a lesser-known corporate governance tool ideally suited for biotech companies and other entities that rely upon scientific data. The SAB can review internal research, vet external communications, and generally serve as an objective and independent advisor on scientific matters. Despite such available utility, biotech business leaders regularly make claims unsupported by scientific reality. The risked result: the government and angry investors bringing suit.

This article aims to explain why SABs failed to prevent investor fraud and its legal fallout at several biotech companies. The introduction provides a background regarding SAB as a potential “shield” against investor fraud, Part I examines the SAB’s role at Theranos, Part II examines the SAB’s role at uBiome, Part III examines the SAB’s role at five lesser-known biotech companies, and Part IV presents conclusions and recommendations based on the findings.

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* J.D., UCLA School of Law Class of 2022; Incoming Associate at Morrison & Foerster LLP

INTRODUCTION

“Listen to the science,” it’s a phrase that many Americans became accustomed to hearing during the pandemic.¹ Some critics interpret it to literally mean, “listen to what scientists say or tell you to do.”² But supporters posit a different interpretation, that scientific data should be used to inform decisions and public statements.³ Unfortunately, many biotech executives have failed to “listen to the science” in either sense, making business claims unsupported by scientific data, and then suffering severe consequences. “Theranos” founder Elizabeth Holmes is the most infamous culprit,⁴ but arguably more dramatic are the “uBiome” founders who fled the United States after also being charged with fraud.⁵ Harkening to Theranos, the SEC and DOJ targeted “Decision Diagnostics” and its CEO for falsely claiming that a finger-prick blood test for COVID was nearing regulatory approval.⁶ Investors also regularly take action, like those who sued “Puma Biotechnology Inc.” for misrepresenting clinical trial data regarding a key drug.⁷

Investor-fraud is not unique to biotech, but these stories demonstrate that biotech leaders do not always “listen to the science.” Why didn’t they listen? The obvious answer is “greed,” but an industry that relies upon scientific data should theoretically have less capacity for fraud. Either the data supports a claim, or it doesn’t.⁸ However, not every biotech entrepreneur is a data scientist. Maybe they saw data as promising, but a more objective scientific eye could see otherwise. Such a miscalculation

¹ James, S. Brady, Press Briefing Room, *Press Briefing by Principal Deputy Press Secretary Karine Jean-Pierre* (Jul. 29, 2021) (available at <https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/29/press-briefing-by-principal-deputy-press-secretary-karine-jean-pierre-july-29-2021/>).

² See Jonah Goldberg, *When ‘Listen to the Science’ Is Just a Shield for Bad Policy Ideas*, DISPATCH, (Dec. 25, 2020), https://thedispatch.com/p/when-listen-to-the-science-is-just?utm_source=url.

³ See Carlo Rovelli, *Politics Should Listen to Science, Not Hide Behind it*, NATURE MATERIAL 20, 272 (Jan. 4, 2021), <https://www.nature.com/articles/s41563-020-00891-3>.

⁴ Bobby Allyn, *Elizabeth Holmes Verdict: Former Theranos CEO is Found Guilty on 4 Counts*, NAT. PUB. RADIO (Jan. 3, 2022, 7:14 PM), <https://www.npr.org/2022/01/03/1063973490/elizabeth-holmes-trial-verdict-guilty-theranos>.

⁵ Christine Smythe, *The Poop-Testing Startup Founder Who Lied to Get on a “30-Under-30” List is Now Officially a Fugitive*, THE BUS. OF BUS. (Dec. 1, 2021, 4:35 PM), <https://www.businessofbusiness.com/articles/poop-testing-startup-ubiomes-founders-are-officially-fugitives-the-us-says-theyre-hiding-in-germany/>.

⁶ Erica T. Jones, *Decision Diagnostics Saga Continues as Investors Bring Suit*, NAT. L. REV. (Mar. 26, 2021), <https://www.natlawreview.com/article/decision-diagnostics-saga-continues-investors-bring-suit>.

⁷ Brendan Pierson, *Puma Biotech Agrees to Pay Investors \$54.2 mln in Fraud Case*, REUTERS (Dec. 14, 2021, 13:17 PMAM), <https://www.reuters.com/legal/government/puma-biotech-agrees-pay-investors-542-mln-fraud-case-2021-12-14/>.

⁸ This assumes of course, that the data wasn’t faked in the first place. See, e.g., Ivan Oransky, *Biotech Co-Founder Faked Data in NIH-Funded Research, Says Federal Watchdog*, RETRACTION WATCH (Aug. 17, 2021), <https://retractionwatch.com/2021/08/17/biotech-co-founder-faked-data-in-nih-funded-research-says-federal-watchdog/>.

clearly carries significant risk, potentially drawing the ire of investors, the SEC, and the U.S. Attorney's Office.⁹ As a result, some biotech founders have become increasingly and understandably concerned regarding investor scrutiny.¹⁰ If the ambitious goals and optimism they pitch to investors is later contradicted by scientific reality, what can protect them from becoming the "next Elizabeth Holmes?"¹¹

Thankfully, a Scientific Advisory Board (SAB) can provide such protection.¹² An SAB is "usually comprised of five to twelve distinguished scientists and physicians" retained as independent consultants.¹³ Unlike a board of directors, SABs typically do not have authority over company policy or management decisions.¹⁴ Instead, SABs often provide a degree of "external validation" for start-ups and informal guidance to executives of more established companies.¹⁵ The most effective SABs are often small, have a clearly defined purpose, and contain a variety of professional expertise.¹⁶ One such clearly defined purpose is to "review the quality and relevance of the scientific and technical information."¹⁷ This is exactly the kind of protection that can help a biotech founder guard against investor suits or government prosecution. If a group of well-respected academics and industry experts have advised you that scientific data supports your business claim, you have a very strong defense against any allegations of fraud. In essence, an effective SAB can be a shield against investor fraud allegations.

Despite this available protection, biotech leaders still clearly face such allegations with some frequency.¹⁸ A possible explanation: the threshold for fraud allegations may naturally be lower within biotech since business claims can be more objectively measured against scientific data.¹⁹ In

⁹ See Allyn, *supra* note 4; Smythe, *supra* note 5; Jones, *supra* note 6; Pierson, *supra* note 7; Oransky, *supra* note 8.

¹⁰ See Jed Kim & Sasha Fernandez, *The Legacy of the Theranos Debacle Weighs Especially Heavy on Women in Biotech*, MARKETPLACE TECH (Aug. 27, 2021), <https://www.marketplace.org/shows/marketplace-tech/the-legacy-of-the-theranos-debacle-weighs-especially-heavy-on-women-in-biotech/>.

¹¹ *Id.*

¹² Bruce Booth, *Biotech Scientific Advisory Boards: What Works, What Doesn't*, FORBES (Sept. 10, 2012, 5:35 PM), <https://www.forbes.com/sites/brucebooth/2012/09/10/biotech-scientific-advisory-boards-what-works-what-doesnt/?sh=d98d072388cf>.

¹³ Jeffery L. Quillen, *Costs and Benefits of Scientific Advisory Boards*, F. REP. (MIT Enter. F. Cambridge, Cambridge, Mass.), Feb. 2004.

¹⁴ *Id.*

¹⁵ Booth, *supra* note 12.

¹⁶ Booth, *supra* note 12; Kevin Pojasek, *Reflections on Scientific Advisory Board Construction*, LIFE SCI VC (May 19, 2015), <https://lifescivc.com/2015/05/reflections-on-scientific-advisory-board-construction/>.

¹⁷ *About the Science Advisory Board (SAB) and the SAB Staff Office*, U.S. ENV'T PROT. AGENCY, <https://www.epa.gov/aboutepa/about-science-advisory-board-sab-and-sab-staff-office> (last visited on Apr. 6, 2022).

¹⁸ Allyn, *supra* note 4; Smythe, *supra* note 5; Jones, *supra* note 6; Pierson, *supra* note 7; Oransky, *supra* note 8.

¹⁹ See generally Bernadette Tansey, *Rise in Biotech Lawsuits / Industry Blames Law Firms Looking for New Targets, but Some Investors Claim Companies Misled Them*, SFGATE (Jan. 26, 2004), <https://www.sfgate.com/business/article/Rise-in-biotech-lawsuits-Industry-blames-law-2827265.php>.

essence, the objectivity of scientific data is a double-edged sword: it's a strong defense for business claims and an equally powerful tool for disgruntled investors. However, it's difficult to say whether biotech is naturally prone to investor fraud claims. "Biotech" is a general term, defined as a "science-driven industry sector that uses living organisms and molecular biology to produce healthcare-related products."²⁰ It technically encompasses everything from pharmaceutical drugs to fermented food products.²¹ While a recent regulatory focus portrays biotech as susceptible to investor fraud,²² a limited empirical study came to a seemingly opposite conclusion.²³ Historically, biotech securities class-action suits were more likely to be dismissed early in litigation when compared to suits from other industries.²⁴ This could imply that investor suits against biotech may have fewer merits, and that investor-fraud is less likely.

Trying to identify a general link between investor fraud and biotech is an extraordinarily broad inquiry and would likely lead to unclear conclusions. Instead, a more limited question can help provide some valuable insight: Why did biotech companies fail to prevent allegations of investor fraud when an SAB can provide such excellent protection? Was the SAB comprised of experts that were too cozy with the business leaders? Was the SAB formed too late? Was the SAB present purely for public relations? This paper aims to answer these questions in the context of some famous and lesser-known biotech companies whose executives were charged with investor fraud. Specifically, this paper analyzes SABs and patterns of misconduct at Theranos, uBiome, and five other biotech companies within the United States. Using these companies as case studies, the paper attempts to identify patterns that prevented the SABs from providing a scientific "check" against business claims that investors later claimed were fraudulent.

Before delving into this analysis, a few key terms require definition. For the purposes of this paper, "investor fraud" will refer to a basic definition: enticing individuals to make financial investments based of false or misleading information.²⁵ While Elizabeth Holmes was specifically

²⁰ Julia Kagan, *Biotechnology*, INVESTOPEDIA (Mar. 8, 2022), <https://www.investopedia.com/terms/b/biotechnology.asp>.

²¹ *Id.*

²² Andrew Boutros, et. al., *Biotech Beware: Increased SEC Focus on COVID-Related Activities and Claims Amplifies the Enforcement Risks for the Unaware or Brazen*, JD SUPRA (Jul. 13, 2020), <https://www.jdsupra.com/legalnews/biotech-beware-increased-sec-focus-on-82454/>.

²³ Doug Greene, et. al., *Myths & Misconceptions of Biotech Securities Claims: An Analysis of Motion to Dismiss Results from 2005-2016*, D&O DISCOURSE (Mar. 14, 2017), <https://www.dandodiscourse.com/2017/03/14/myths-misconceptions-of-biotech-securities-claims-an-analysis-of-motion-to-dismiss-results-from-2005-2016/> (finding that federal securities claims are often dismissed "at an early stage in litigation.").

²⁴ *Id.*

²⁵ See generally Federal Bureau of Investigation, *Securities Fraud Awareness and Prevention Tips*, <https://www.fbi.gov/stats-services/publications/securities-fraud> (last visited on Apr. 6, 2022); Terry Tuner, *Investment Fraud*, CONSUMERNOTICE.ORG, (Nov. 2, 2021),

convicted of criminal wire fraud,²⁶ there are important legal distinctions between criminal and civil fraud allegations.²⁷ The substantive underlying facts are as follows: a business leader lied to potential investors about the prospects or performance of their company, and investors bought a stake in the company due to this false information. This core fact pattern will be referred to as “investor fraud,” independent of the actual civil or criminal charges filed.

Second, any group of scientists, academics, or other industry experts that are retained by a company as independent consultants will be referred to as an SAB. Some organizations and biotech companies refer to these groups as a “Scientific Advisory Panel”²⁸ or “Scientific Advisory Committee.”²⁹ However, their core responsibilities and makeup are the same: experts employed outside the company that provide an independent assessment of scientific data and/or communications.³⁰ Thus, even if a company uses different terminology, it will be referred to as an SAB for the purposes of this paper.

Third and finally, the term “business leader” will be used to refer to company CEOs, presidents of the board of directors, founders, and controlling investors who make executive management decisions. While these roles are distinct in established companies, they often overlap in smaller start-ups.³¹ In this paper, the most essential role of a “business leader” is that they communicate directly to potential investors and have authority within the company to make managerial decisions. The level of internal information access will *not* be a defining characteristic, since determining when a business leader actually knew key information can be the ultimate source of controversy in biotech fraud cases.³²

<https://www.consumernotice.org/data-protection/fraud-and-scams/investment/>; Christine N. Kieffer & Gary R. Mottola, *Understanding and Combating Investment Fraud* 274 (Pension Rsch. Council at The Wharton Sch., Working Paper, 2016), <https://pensionresearchcouncil.wharton.upenn.edu/wp-content/uploads/2017/02/WP2016-19-Kieffer-and-Mottola.pdf>.

²⁶ Erin Griffith, *Elizabeth Holmes is Set to be Sentenced on Sept. 26*, N.Y. TIMES (Jan. 12, 2022), <https://www.nytimes.com/2022/01/12/technology/elizabeth-holmes-theranos-sentencing.html#:~:text=Holmes%2C%20who%20was%20found%20guilty,be%20filed%20by%20March%204>.

²⁷ See generally FindLaw, *Everything You Need to Know About Fraud Crimes and Fraud Law*, FINDLAW, <https://www.findlaw.com/criminal/criminal-charges/fraud.html> (last updated June 1, 2022).

²⁸ *Physical Therapy Outcomes Registry Scientific Advisory Panel*, PHYSICAL THERAPY OUTCOMES REGISTRY, <https://www.ptoutcomes.com/sap> (last visited Sept. 29, 2022).

²⁹ *Scientific Advisory Committee*, BILL AND MELINDA GATES FOUND. (Apr. 6, 2022), <https://www.gatesfoundation.org/about/leadership/scientific-advisory-committee>.

³⁰ *Id.*

³¹ See NOAM WASSERMAN, *THE FOUNDER’S DILEMMAS: ANTICIPATING AND AVOIDING THE PITFALLS THAT CAN SINK A STARTUP* 124 (2013).

³² Yasmin Khorram, *Elizabeth Holmes Knew Machines Weren’t Working, Former Theranos Lab Director Testifies*, CNBC (Oct. 1, 2021), <https://www.cnbc.com/2021/10/01/elizabeth-holmes-knew-machines-werent-working-says-ex-lab-director.html> (government’s key witness testified that Elizabeth Holmes knew lab machines weren’t working at the time she pushed ahead with a launch).

I. THERANOS: TOO LITTLE TOO LATE

A. *The Dramatic Rise and Fall*

“Theranos” is undoubtedly the most infamous case of biotech fraud in modern history. Documentaries, books, and TV series have been based on the meteoric rise and fall of its founder, Elizabeth Holmes.³³ At the most basic level, Holmes aimed to provide a myriad of blood tests with technology that used an extremely small sample of blood.³⁴ Holmes dropped out of Stanford in 2003 to pursue the project full-time, eventually named the resulting company “Theranos,” and raised hundreds of millions of dollars in the following decade.³⁵ Holmes herself became a prominent public figure, regularly featured in major publications and invited to events with Obama administration officials.³⁶ At its peak, Theranos was valued at \$9 billion, backed by major venture capital firms, and advertised an especially prestigious board of directors.³⁷

However, the technology Theranos developed to actually run the blood tests was faulty at best. In fact, their blood-testing machines were often totally inoperable and would only simulate running tests, giving patients fake test results.³⁸ To conduct actual tests, Theranos employees diluted their very small blood samples and ran tests on commercial analyzers.³⁹ The results were often inaccurate, sometimes providing doctors and patients with startling misdiagnoses.⁴⁰ Eventually in October 2015, the compounding fraud was exposed by investigative journalist John Carreyrou, a story he later turned into the authoritative book on Theranos’ rise and fall.⁴¹

The fallout was severe and incremental. Theranos fervently fought the story’s allegations, but began to shut down labs under newly intensified

³³ See THE INVENTOR: OUT FOR BLOOD IN SILICON VALLEY (HBO 2019); PHIL C. SENIOR, BILLION DOLLAR FAÇADE: THE RISE AND FALL OF THERANOS AND ELIZABETH HOLMES (2019); NOLAN C. HANSON, THE STORY OF ELIZABETH HOLMES: THE SPECTACULAR RISE AND DOWNFALL OF THE THERANOS ORGANISATION (2022); THE DROPOUT, (Hulu 2022).

³⁴ John Carreyrou, *Blood-Testing Firm Theranos to Dissolve*, WALL ST. J. (Sept. 5, 2018), <https://www.wsj.com/articles/blood-testing-firm-theranos-to-dissolve-1536115130>.

³⁵ See JOHN CARREYROU, BAD BLOOD: SECRETS AND LIES IN A SILICON VALLEY STARTUP 13 (2018).

³⁶ *Id.* at 219, 260.

³⁷ *Id.* at 206.

³⁸ See *id.* at 226.

³⁹ See *id.*

⁴⁰ See JOHN CARREYROU, BAD BLOOD: SECRETS AND LIES IN A SILICON VALLEY STARTUP 233–35 (2018); Yasmin Khorram, *Former Theranos Patient Testifies that a Blood Test at Walgreens Came Back with False Positive for HIV*, CNBC (Nov. 17, 2021), <https://www.cnn.com/2021/11/17/theranos-patient-says-blood-test-came-back-with-false-positive-for-hiv.html>.

(among the most dramatic, one patient was misdiagnosed with a sexually transmitted disease).

⁴¹ See CARREYROU, *supra* note 34 at 301; John Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*, WALL ST. J. (Oct. 16, 2015), <https://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901>.

scrutiny from federal regulators and investors.⁴² As commercial partners backed out and regulators revoked approvals, Theranos laid off employees, quietly settled legal threats from investors, and sought bankruptcy protection.⁴³ Finally in September 2018, after Holmes and her co-founder were charged in civil and criminal court, Theranos was officially shuttered.⁴⁴ Holmes was later convicted on three counts of criminal wire fraud and one count of conspiracy to commit wire fraud.⁴⁵ In November 2022, Holmes was sentenced to eleven years and three months in federal prison for her conviction.⁴⁶

B. SAB as an Afterthought

Given the intense drama surrounding Theranos, it's no surprise that numerous books and movies have been based on the saga.⁴⁷ But it is surprising that in Carreyrou's authoritative telling, there is practically no mention of the SAB.⁴⁸ This is less surprising after learning that Theranos did not form an SAB until April 2016, a full six months *after* Carreyrou published his findings in the Wall Street Journal.⁴⁹ The eventual co-director of Theranos' SAB had encouraged the company for years to form an official SAB, but Holmes and others ignored the advice until a credibility crisis emerged.⁵⁰ In the case of Theranos, the SAB was truly an afterthought. While some medical professionals had been previously placed in leadership roles, their presence was nominal.⁵¹

Thus, the first and most obvious lesson Theranos offers: form an SAB before your company is valued at \$9 billion. While each new valuation and round of funding heightened the company's fervor and momentum, it also

⁴² See CARREYROU, *supra* note 34 at 289; John Carreyrou, *Theranos Lays Off Most of Its Remaining Workforce*, WALL ST. J. (Apr. 10, 2018), <https://www.wsj.com/articles/theranos-lays-off-most-of-its-remaining-workforce-1523382373>.

⁴³ See CARREYROU, *supra* note 34, at 289 (2018); Carreyrou, *supra* note 42; John Carreyrou, *Blood-Testing Firm Theranos Gets \$100 Million Lifeline From Fortress*, WALL ST. J. (Sep. 5, 2018) <https://www.wsj.com/articles/blood-testing-firm-theranos-gets-100-million-lifeline-from-fortress-1514057523>.

⁴⁴ Carreyrou, *supra* note 34.

⁴⁵ Allyn, *supra* note 4.

⁴⁶ Erin Griffith, *Elizabeth Holmes is Sentenced to More Than 11 Years for Fraud*, N.Y. TIMES (Nov. 18, 2022) <https://www.nytimes.com/2022/11/18/technology/elizabeth-holmes-sentence-theranos.html>.

⁴⁷ Emma Dibdin, *The Best Books, Movies, Podcasts, and TV Shows About Elizabeth Holmes & Theranos*, TOWN & COUNTRY (Mar. 3, 2022) <https://www.townandcountrymag.com/leisure/arts-and-culture/g38762130/elizabeth-holmes-podcasts-tv-shows/>.

⁴⁸ *Id.*

⁴⁹ Lydia Ramsey Pflanzler, *Theranos just made a crucial move that could help its reputation*, BUS. INSIDER (Apr. 7, 2016), <https://www.businessinsider.com/theranos-adds-members-to-scientific-and-medical-advisory-board-2016-4>.

⁵⁰ *Id.*

⁵¹ Yasmin Khorrani, *Theranos Hired Its President's Dermatologist as Lab Director in 2014, Testimony Shows*, CNBC (Oct. 14, 2021), <https://www.cnbc.com/2021/10/14/theranos-hired-sunny-balwanis-dermatologist-as-lab-director-in-2014.html> (the co-founder's personal dermatologist who lacked board certification was made a lab director; he went to the lab twice, and never met any employees, physicians, or patients).

brought increased risk of investor blowback.⁵² A firm providing millions of dollars isn't likely to quietly accept a loss, regardless of blatant fraud. Yet before 2016, Theranos' only advisory panel consisted of individuals more suited to secure government connections than provide industry insight.⁵³ This was a failure of the existing directors and business leaders to recognize the risk that accompanied huge venture capital investments and the resulting requirement to scrutinize its existing technology more intensely.⁵⁴ Unfortunately, it's unclear whether such scrutiny was even possible before 2016.

C. Compartmentalizing Critics

Some of Theranos' most vocal skeptics were not investors or medical experts, but employees. Most famous among them is Tyler Shultz, the grandson of George Shultz, a former U.S. Secretary of State and Theranos director.⁵⁵ While Tyler was not the only whistle-blower at the company, he was among the most vocal and had a direct line to the company's leadership.⁵⁶ Tyler's story is like many others employees': he joined Theranos largely due to Holmes' charisma and vision, discovered alarming oversights and misrepresentations, and resigned when it became clear the company would not take corrective action.⁵⁷

What these employees did not see were the strategic efforts to create firewalls between Theranos' departments and prevent information sharing: biochemists and engineers were told to not communicate with each other, engineers were not permitted to look inside Theranos' technology, software engineers were forbidden from designing error messages, employee departures were rarely announced or explained, and *all* information from various departments was filtered through Holmes.⁵⁸ The grip on information was so tight, that Holmes actually likened her vision to blind,

⁵² The clear lack of medical oversight potentially makes Theranos' investors less sympathetic victims, as venture capital firms that specialized in biotech were skeptical from the start and avoided investing with Holmes. See CARREYROU, *supra* note 34 at 274.

⁵³ Kanika Sinha, *What the Theranos Scandal Reveals About the Role of the Startup Advisory Board*, ESCALON (Oct. 28, 2021), <https://escalon.services/blog/what-the-theranos-scandal-reveals-about-the-role-of-the-startup-advisory-board/#:~:text=The%20Theranos%20advisory%20board,the%20health%20care%20technology%20sector.>

⁵⁴ *Id.*

⁵⁵ Bobby Allyn, *Theranos Whistleblower Celebrated Elizabeth Holmes Verdict by 'Popping Champagne'*, NAT. PUB. RADIO (Jan. 5, 2022), [https://www.npr.org/2022/01/05/1070474663/theranos-whistleblower-tyler-shultz-elizabeth-holmes-verdict-champagne.](https://www.npr.org/2022/01/05/1070474663/theranos-whistleblower-tyler-shultz-elizabeth-holmes-verdict-champagne)

⁵⁶ George Shultz did not initially believe Tyler, leading to a multi-generational family drama full of aggressive lawyers and pleadings for Tyler to rescind his whistle-blowing statements. Eventually, grandfather and grandson made amends when it became clear Holmes had lied. See Allyn, *supra* note 55; See CARREYROU, *supra* note 34 at 240–247, 288.

⁵⁷ Allyn, *supra* note 55; see generally CARREYROU, *supra* note 34.

⁵⁸ CARREYROU, *supra* note 34 at 20, 21, 25, 172, 186, 214, 215.

religious faith.⁵⁹ Questioning it was undoubtedly a mortal sin, resulting in swift dismissal.⁶⁰

In essence, Holmes designed the company to avoid horizontal transparency. Information was only filtered up and ultimately to Holmes, rather than across various departments. This compartmentalization meant that even if an SAB was in place, information would have still been “filtered” through Holmes. While business leaders should remain informed regarding what their SAB sees, they should *not* be the messenger. Transparency between departments and with an SAB would have likely provided an earlier, clearer picture regarding Theranos’ problems. The second lesson: promote internal transparency among departments and unfiltered communication to the SAB. The importance of this second lesson is better demonstrated by another biotech firm that gained prominence around the same time but was more interested in feces than blood.

II. MICROBIAL FUGITIVES

A. SAB in Name Only

In 2014, Gabe Foster was feeling increasingly uneasy at his job.⁶¹ He had a background in biochemistry and was the head laboratory technician for uBiome, a startup that took customers’ stool samples and provided data on the trillions of microbes that lived within their body.⁶² This microbial makeup is sometimes referred to as a “microbiome,” explaining the startup’s catchy name.⁶³ Foster was the in-house expert on running the lab, but was concerned that customers were provided information without proper context and that investors were promised unrealistic clinical applications.⁶⁴ Foster’s professional opinion was that “there was no clinical application for a test like [uBiome’s].”⁶⁵

When Foster took his concerns to one of uBiome’s co-founders, Zac Apte, he was fired.⁶⁶ Unbeknownst to Foster, at least one member of uBiome’s SAB later shared his concerns.⁶⁷ Unlike Theranos, uBiome had a respectable SAB in place during its early stages.⁶⁸ In 2013, just one year

⁵⁹ *Id.* at 173.

⁶⁰ *Id.* at 4, 8 (2018) (Holmes immediately fired an experienced financial executive when he first brought concerns that their representations to investors wasn’t entirely accurate).

⁶¹ The Journal, *What Went Wrong at uBiome, Part I*, WALL ST. J. (Nov. 5, 2021), <https://www.wsj.com/podcasts/the-journal/what-went-wrong-at-ubiome-part-1/8b0717aa-1c66-4524-b47f-0cd3a399fcae>.

⁶² *Id.*

⁶³ *Id.* (they also advertised themselves as the “23andMe” of poop).

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.* (SAB member Jonathan Eisen was similarly concerned with official representations that uBiome’s test results were “medically informative”).

⁶⁸ Pflanzner, *supra* note 49 (Theranos did not have a formal SAB in place until almost 13 years after its founding and amid increasing public scrutiny. This group was made up of both practicing medical doctors and science professors); *Our Story*, UBIOME (Mar. 31, 2019), <https://ubiome.com/about-us/>

after uBiome's launch, Apte reached out to a critic of the company, UC Davis Professor Jonathan Eisen.⁶⁹ He was receptive to Professor Eisen's criticism and asked for help, inviting the prominent academic to join the company's SAB.⁷⁰ The SAB eventually grew to almost three dozen members that included prominent names like geneticist George Church from Harvard.⁷¹

Despite the SAB's expertise and uBiome proudly touting the prominent names it featured, the SAB members were tasked with vetting public communications rather than scientific data.⁷² Professor Eisen resigned from the board in 2016 when the company's messaging departed from his professional opinion.⁷³ Eisen agreed with Foster, that uBiome "had no evidence that they could [provide diagnostic information] for people."⁷⁴ He felt increasingly uncomfortable being associated with uBiome, and stepped down from the SAB after citing vague conflicts.⁷⁵ Yet the company kept showing Eisen's name on the SAB for over a year, all while pushing "clinical tests" that customers could charge to insurance after filling out an online checklist.⁷⁶ Eventually, Eisen was forced to publicly admonish the company for still including his name on their SAB.⁷⁷ It seems that the public embarrassment finally got uBiome to remove his name.⁷⁸

B. A Familiar Downfall with a Twist

Eventually, it wasn't a journalist or insider that brought uBiome under greater scrutiny, but a disgruntled customer. Damian Moskowitz had suffered from irritable bowel syndrome for years, and was initially enthusiastic about uBiome's products.⁷⁹ But he grew skeptical of the test's utility since it did not help his doctors, and even more skeptical of how

[<https://web.archive.org/web/20190331140522/https://ubiome.com/about-us/>] (According to a previous version of its website, uBiome's SAB was in place by, or shortly after, its founding).

⁶⁹ The Journal, *supra* note 61.

⁷⁰ *Id.*

⁷¹ *Science*, UBIOME (Apr. 2, 2019), <https://ubiome.com/science/>

[<https://web.archive.org/web/20190402140931/https://ubiome.com/science/>].

⁷² The Journal, *supra* note 61.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.* (Eisen wanted to avoid making a "public stink" regarding his departure).

⁷⁶ The Journal, *supra* note 61. (Eisen repeatedly contacted the company, even stating that he "anti-endorsed" uBiome practices); Zachary Apte (@zacharyapte), TWITTER (Jul. 3, 2017, 10:35 PM), <https://twitter.com/zacharyapte/status/882065388443283457>.

⁷⁷ The Journal, *supra* note 61 (Eisen took to Twitter to express his frustration, Apte responded to the tweet later that day); Jonathan Eisen (@phylogenomics), TWITTER (Jul. 3, 2017, 10:00 PM), <https://twitter.com/phylogenomics/status/882056419368816640>.

⁷⁸ The Journal, *supra* note 61; Zachary Apte (@zacharyapte), [Twitter] (Jul. 3, 2017, 10:35 PM), <https://twitter.com/zacharyapte/status/882065388443283457>.

⁷⁹ The Journal, *What Went Wrong at uBiome, Part 2*, WALL ST. J. (Nov. 12, 2021), <https://www.wsj.com/podcasts/the-journal/what-went-wrong-at-ubiome-part-2/17d62c32-7c70-4e35-afc5-524a428c5a10>.

easy it was to have the test covered by insurance.⁸⁰ Moskowitz happened to have extensive knowledge regarding medical insurance billing practices and the many ways that providers try to “game” the system for their financial benefit.⁸¹ After conducting extensive research, he was convinced that uBiome was selling a fool’s gold version of a clinical test and filed a complaint with regulators.⁸² The complaint coincided with insurance companies’ suspicions, culminating in April 2019.⁸³

At that point, the FBI raided uBiome’s headquarters and the board immediately placed Apte and the other co-founder, Jessica Richman, on leave.⁸⁴ The general counsel took over as interim CEO, and assured employees that “it’s not the science, it’s the billing.”⁸⁵ Later, it was revealed that Apte and Richman secretly would “upgrade” tests for patients by simply ordering a “re-test” of a sample, rather than actually running a new test on a new sample.⁸⁶ In addition, some doctors who allegedly approved requests for clinical tests were simply fake.⁸⁷ Unsurprisingly, most employees were fired and the company shuttered in October 2019.⁸⁸

But unlike Holmes, Apte and Richman have not seen their day in court. According to court documents filed by the government, Apte and Richman married in 2019, had their marriage certified in June 2020, and left for Germany a few days later, a country where Apte was also a citizen.⁸⁹ Through lawyers, Apte claimed to be a “caretaker” for Richman, and further claimed that they were unable to travel to the United States for an appearance in court.⁹⁰ As of February 2022, their exact location in Germany was still unknown.⁹¹

⁸⁰ *Id.*; Anna Wilde Mathews & Amy Dockser Marcus, *Microbiome Testing Startup Under Scrutiny for Billing Practices*, WALL ST. J. (Apr. 26, 2019, 8:58:00 PM), <https://www.wsj.com/articles/ubiome-offices-searched-by-fbi-11556301287>.

⁸¹ See The Journal, *supra* note 79.

⁸² *Id.* (in addition to filing an eight-page complaint with the California Medical Board, Moskowitz contacted the Wall Street Journal reporter who broke the Theranos story, John Carreyrou).

⁸³ The Journal, *supra* note 79; Sarah Sharples, *Fugitive Founders of Medical Company uBiome Face Charges of Defrauding Investors*, NEWS.COM.AU (Mar. 22, 2021, 1:07 AM), <https://www.news.com.au/finance/business/technology/fugitive-founders-of-medical-company-ubiome-face-charges-of-defrauding-investors/news-story/d5b61063a0051cf07b8dfe4e470c6ac9>.

⁸⁴ The Journal, *supra* note 79; Press Release, Jennifer Gersetenberger, UBIOME, *uBiome Appoints John Rakow as Interim Chief Executive Officer* (May 1, 2019), https://www.prweb.com/releases/ubiome_appoints_john_rakow_as_interim_chief_executive_officer/prweb16281825.htm; Anna Wilde Mathews & Amy Dockser Marcus, *Microbiome Testing Startup Under Scrutiny for Billing Practices*, WALL ST. J. (Apr. 26, 2019, 8:58 PM), <https://www.wsj.com/articles/ubiome-offices-searched-by-fbi-11556301287>.

⁸⁵ The Journal, *supra* note 79; Securities Exchange Commission v. Richman, No. 21-cv-01911-CRB, 2021 WL 5113168, at *2 (N.D. Cal. Nov. 3, 2021).

⁸⁶ The Journal, *supra* note 79; *SEC v. Richman*, 2021 WL 5113168, at *2.

⁸⁷ The Journal, *supra* note 79.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ The Journal, *supra* note 79; Synapse, *From UCSF Start-Up to Fugitives from Justice*, UCSF STUDENT VOICES (Feb. 28, 2022), <https://synapse.ucsf.edu/articles/2022/02/28/ucsf-start-fugitives-justice>.

C. SAB Kept in the Dark

In a real sense, uBiome's general counsel was correct that "science" wasn't the problem. Unlike Theranos, uBiome provided real test results to patients.⁹² However, they incorrectly sold the results as medically useful and, more importantly, reimbursable by insurance.⁹³ Therefore, while the SEC charged them with investor fraud, their criminal charges actually stem from the \$300 million falsely billed to insurers, rather than defrauding investors.⁹⁴ So instead of "sister" companies, Theranos and uBiome are perhaps better described as "cousin" biotech frauds.

Whatever its relation to Theranos, uBiome offers a clarifying lesson regarding SABs. Simply having an SAB in place, even a well-qualified one, is not "automatic" protection against allegations of investor fraud. It cannot just be an outward facing body, solely tasked with increasing the legitimacy of the company's image. An SAB must also provide *internal* checks, only possible when people like Gabe Foster can directly communicate with SAB members, rather than having their concerns quashed by leadership. Foster articulated the *exact* same concern held by Professor Eisen two years earlier.⁹⁵ During those two years, uBiome began to market the new test that ultimately drew the ire of regulators and insurers.⁹⁶ If Foster had first contacted Professor Eisen, perhaps uBiome's downfall could have been avoided. While a speculative hope, uBiome at least informs what is *not* an effective use of an SAB.

The second lesson from Theranos is reinforced by uBiome: promote internal and horizontal transparency with the SAB. While uBiome did not necessarily have formal internal firewalls, "the culture was very secretive."⁹⁷ An employee hired as a "citizen scientist in residence" was denied access to the company's test database and said that no one wanted to answer his questions.⁹⁸ He summarized, "[secrecy] was a general trend within the company... you felt like you weren't really allowed to ask questions."⁹⁹ Another employee described that there was "no power beyond Zac and Jessica."¹⁰⁰ Like Holmes, Apte and Richman tightly controlled information and dismissed those who pushed back too much, but via a business culture rather than structure. Their lack of transparency and poor SAB utilization ultimately doomed the company and made them legal targets, despite forming a competent SAB at the correct time.

⁹² The Journal, *supra* note 79.

⁹³ *Id.*

⁹⁴ *Id.* (insurers claim to have actually paid \$35 million in falsified charges; Apte and Richman raised around \$81 million from investors during the life of the company).

⁹⁵ The Journal, *supra* note 61; The Journal, *supra* note 79.

⁹⁶ The Journal, *supra* note 61.

⁹⁷ The Journal, *supra* note 61; The Journal, *supra* note 79 (both Gabe Foster and Richard Sprague, employed at different times and in different departments, used this exact language).

⁹⁸ The Journal, *supra* note 61.

⁹⁹ *Id.*

¹⁰⁰ The Journal, *supra* note 79.

III. MIRACLE DRUGS, FAKE TRIALS, AND DEFUNCT SABS

Unfortunately, dramatic and entertaining publications related to biotech fraud are limited, despite the seeming abundance of material. Without the work of investigative journalists, the inner dealings of other biotech companies charged with investor fraud are less clear. Piecing together the puzzle requires a closer look at court filings, regulatory announcements, and public-facing information regarding the companies. Thankfully, the available information at least offers indicators that Theranos and uBiome are not unique regarding their SAB failures.

A. *Remune's Legacy*

First, an older example of biotech fraud may offer some historical perspective. Dr. Jonas Salk, a pioneer of polio vaccination, co-founded the Immune Response Corporation (IRC) in 1987 with a lofty goal: develop a cure for AIDS.¹⁰¹ Over the following years, the company slowly developed “Remune,” a product originally meant to boost the immune system of those already infected with HIV.¹⁰² IRC gained substantial public goodwill from its association with Dr. Salk and proximity to UCSD, a hub for biotech talent.¹⁰³ The goodwill created enormous stock value as the company went public in 1990, even though it did not yet have a viable product.¹⁰⁴

However, insiders at the company already knew that Remune was largely ineffective.¹⁰⁵ The first FDA-approved study of Remune began in 1996, but was halted in May 1999 “on the recommendation of a five-member Data Safety Monitoring Board (DSMB) selected to help review statistics on patients’ responses.”¹⁰⁶ The independent researchers who led the study were “flabbergasted” when IRC pushed back publishing the study’s findings, a cover-up effort they described as “unacceptable.”¹⁰⁷ Despite legal threats from IRC, the researchers published their findings in the November 2000 issue of the *Journal of the American Medical Association (JAMA)*.¹⁰⁸ Once word got out, IRC’s stock plummeted.¹⁰⁹

¹⁰¹ Don Bauder, *San Diego's Biotechs Soared, Then Came Down to Reality*, SAN DIEGO READER (Aug. 29, 2018), <https://www.sandiegoreader.com/news/2018/aug/29/city-lights-biotech-research-hardly-unbiased> (Salk died in 1995, before any of the allegedly fraudulent behavior occurred; the entire company was based on a hypothesis Salk detailed in an article published in the 1987 volume of *Nature*).

¹⁰² *Id.*

¹⁰³ See Bradley J. Frikes, *San Diego Shows Path to Biotech Success*, THE SAN DIEGO UNION TRIB. (Sept. 13, 2015), <https://www.sandiegouniontribune.com/business/biotech/sdut-what-makes-a-biotech-hub-la-2015sep13-story.html>.

¹⁰⁴ Chris Kraul, *Salk Company Files for First Stock Offering*, L.A. TIMES (Apr. 3, 1990), <https://www.latimes.com/archives/la-xpm-1990-04-03-fi-514-story.html>.

¹⁰⁵ Bauder, *supra* note 101.

¹⁰⁶ Susan Haack, *Scientific Secrecy and “Spin”: The Sad, Sleazy Saga of the Trials of Remune*, 69 L. & CONTEMP. PROBS. 47, 55 (2006).

¹⁰⁷ *Id.* at 56.

¹⁰⁸ *Id.* at 57.

¹⁰⁹ *Id.* at 58.

Most shareholders became irate, and many began to bring suit.¹¹⁰ In an ironic foreshadowing of future fraud, Alan Auerbach stood by IRC and stressed that the company's ties with Pfizer proved Remune's promise.¹¹¹ Auerbach's confident stance had been echoed by IRC executives for years, defying experts who said Remune had shown disappointing results from the beginning.¹¹² The legal saga continued for years, eventually resulting in the bankruptcy and liquidation of the company in 2008.¹¹³

So where was the SAB? It's notable that Salk was actually invited to become the "lead scientific advisor" at IRC, so it appears he also founded the company's SAB.¹¹⁴ Unfortunately, the SAB may have also died with Salk in 1995. No SEC filings, press releases, or court filings ever mention an active SAB. In a telltale sign that no SAB was in place, Charles Engelberg advised clients to sell IRC and said, "I've been following [IRC] since 1993 and the company has been guilty of massaging data all along..."¹¹⁵ No one was apparently vetting the company's data. Perhaps association with Salk made business leaders overly confident or overly optimistic. But in either case, it appears name recognition was their only protection against fraud allegations. The only independent experts that interacted with IRC business leaders, those that ran the FDA-approved study, found their behavior "unacceptable."¹¹⁶ The SAB at IRC was either never created, or became defunct upon Salk's death. Thus, the important lesson of forming an SAB at the appropriate growth stage is reiterated, but with a caveat. Make sure the SAB is maintained, even if you have a world-famous scientist as your co-founder.

B. Puma Biotechnology

In December 2021, Puma Biotechnology agreed to pay investors \$54 million in a suit where disgruntled investors claimed that the company's CEO, Alan Auerbach, knowingly misrepresented clinical trial results to investors.¹¹⁷ This was the same Alan Auerbach who defended IRC's reputation when an attempted cover-up became public.¹¹⁸ The plaintiff's lawyer detailed how Auerbach doctored FDA meeting minutes to say their drug had an improved efficacy of 8.4%, instead of its actual improved

¹¹⁰ *Id.* at 60–61.

¹¹¹ *Id.* at 59 (IRC had licensed marketing rights for Remune to a unit of Pfizer); *see infra* section IV.B.

¹¹² Erid Vazquez, *Remune Bites the Dust... Again*, THE BODY PRO (Sept. 30, 2001), <https://www.thebodypro.com/article/remune-bites-dust>; Haack, *supra* note 106, at 61.

¹¹³ L.A. TIMES: Wire Service, *Failed Vaccine, Then Bankruptcy*, L.A. TIMES (Oct. 16, 2008), <https://www.latimes.com/archives/la-xpm-2008-oct-16-fi-briefs16.s3-story.html>.

¹¹⁴ Charlotte DeCroes Jacobs, *JONAS SALK: A LIFE* 432 (2015) ("He agreed to serve as a consultant and advisory board chairman for their new company, Immune Response Corporation").

¹¹⁵ Eric Niiler, *Company, Academics Argue over Data*, 18 NAT. BIOTECHNOLOGY 1235, 1235 (2000).

¹¹⁶ Haack, *supra* note 106, at 56.

¹¹⁷ Pierson, *supra* note 7.

¹¹⁸ Haack, *supra* note 106, at 59.

efficacy of 2.3%.¹¹⁹ After advertising the results as a breakthrough in oncology therapy, Puma sold an additional 1.5 million shares of stock for approximately \$218 million.¹²⁰ Once the truth regarding the drug's efficacy and serious side effects were revealed, the stock dropped over 80%, but only after a number of Puma employees, including Auerbach, had sold much of their stock.¹²¹

While the actual fraud here is fairly cut and dry, the role of the SAB is less clear. Puma touts an eleven-person SAB full of academics and practicing oncologists.¹²² So, at least on paper, the formation and quality of the SAB is not an issue. However, assuming the facts occurred as the plaintiffs claim, the lack of internal transparency blocked the SAB from actually performing its protective function. Instead of the SAB reviewing an important disclosure from the FDA, the CEO exercised exclusive control over the document and doctored it for his needs.¹²³ In addition, neither the corporate governance guidelines nor the code of business ethics make any mention of the SAB.¹²⁴ Not only was the SAB kept in the dark, it had no clearly defined purpose. Again, a business leader appeared to have exercised exclusive control over the dissemination of key information, highlighting the need for transparency internally and with the SAB.

C. PixarBio

Frank Reynolds, the founder and former CEO of PixarBio, was sentenced to seven years in prison and a \$7.5 million fine for defrauding investors.¹²⁵ Reynolds and his associates had hyped up the company's non-opioid pain reliever, "NeuroRelease."¹²⁶ They claimed that FDA approval was only two years away and it would totally replace morphine, despite having not moved past preclinical testing.¹²⁷ While this may sound like standard puffery, Reynolds went a step further and claimed that the drug

¹¹⁹ Transcript of Record at 20, 21, *Hsu v. Puma Biotechnology*, No. 8:15-cv-00865 (C.D. Cal. June 3, 2015).

¹²⁰ *Id.* at 23.

¹²¹ Transcript of Record at 25, *Hsu v. Puma Biotechnology*, No. 8:15-cv-00865. (among the side effects were serious bouts of diarrhea, something especially troubling for cancer patients already potentially suffering from malnourishment due to chemotherapy); *Puma Biotechnology, Inc Common Stock (PBYI)*, NASDAQ, <https://www.nasdaq.com/market-activity/stocks/pbyi> (last visited Aug. 22, 2022).

¹²² Puma Biotechnology, Inc., *Scientific Advisory Board of Puma Biotechnology, Inc.*, https://www.pumabiotechnology.com/docs/corpgov/cg2019/pdf/Scientific_Advisory_Board.pdf.

¹²³ Transcript of Record at 20, 21, *Hsu v. Puma Biotechnology*, No. 8:15-cv-00865.

¹²⁴ Puma Biotechnology, Inc., *Corporate Governance Guidelines* (Nov. 20, 2019), https://www.pumabiotechnology.com/docs/corpgov/cg2020/112019_Puma_Corporate_Governance_Guidelines_104781866_6_US-DOCS.pdf; Puma Biotechnology Inc., *Puma Code of Business Conduct and Ethics*, https://www.pumabiotechnology.com/docs/corpgov/cg2021/042321_Puma_Code_of_Business_Conduct_and_Ethics.pdf.

¹²⁵ Alex Keown, *PixarBio Founder Sentenced to 7 Years in Prison for Defrauding Investors*, BIOSPACE (Feb. 19, 2020), <https://www.biospace.com/article/pixarbio-founder-frank-reynolds-sentenced-to-7-years-in-prison-for-securities-fraud/>.

¹²⁶ *Id.*

¹²⁷ *Id.*

actually helped cure his paralysis after a traumatic injury.¹²⁸ In fact, Reynolds had never been paralyzed or traumatically injured.¹²⁹

Instead, one of Reynold's longtime friends admitted to the investigators that they wanted to inflate the startup's stock price and trading volume to achieve a merger with another entity, InVivo.¹³⁰ Reynolds had co-founded InVivo, but abruptly walked away from that venture in August 2013, and started PixarBio just three months later.¹³¹ High-level employees had quit InVivo because "Reynolds was almost a caricature of a hard-driving, profane, abusive boss."¹³² In his hostile bid to acquire InVivo, Reynolds offered \$77 million in PixarBio stock and insisted that two board members and the interim CEO step down.¹³³ In announcing the takeover bid, Reynolds also alluded to actually being the inventor of InVivo's core technology.¹³⁴ Thus, the entire saga appears to be a failed personal vendetta against some former colleagues.

It also appears as if PixarBio never had a functioning or legitimate SAB. In SEC filings, PixarBio disclosed a 15% stake in the company by one of its SAB members, Dr. Robert Langer, an academic associated with a number of biotech startups.¹³⁵ This isn't necessarily concerning, since paying SAB members in equity is common practice, and Langer had a reputation for starting "companies as quickly as most people order lunch."¹³⁶ But Dr. Armer Khalil, the only other SAB member publicly mentioned, then became Medical Director at PixarBio in 2015.¹³⁷ Dr. Jason Criscione mentioned an "incredibly talented PixarBio Science Advisory

¹²⁸ *Id.*

¹²⁹ Keown, *supra* note 125; Pierson, *supra* note 7 (Reynolds did injure his back unloading a truck at one point and had complications from back surgery, but was never paralyzed; Reynolds also allegedly compared himself to Jesus Christ and Steve Jobs on occasion).

¹³⁰ Jonathan Saltzman, *Associate of PixarBio founder pleads guilty in fraud scheme*, BOS. GLOBE (Feb. 11, 2019), <https://www.bostonglobe.com/business/2019/02/11/associate-pixarbio-founder-pleads-guilty-fraud-scheme/g0N1rCKkxxk66EIQ5PnbUI/story.html>.

¹³¹ Amanda Pedersen, *PixarBio Ups the Ante for InVivo, Strings Attached*, MED. DEVICE AND DIAGNOSTIC INDUS.: QMED NEWS (Jan. 5, 2017), <https://www.mddionline.com/business/pixarbio-ups-ante-invivo-strings-attached>.

¹³² Derek Lowe, *The Dark Side of a Wonderful Investment Story*, AM. ASS'N FOR THE ADVANCEMENT OF SCI. (Sep. 10, 2018), <https://www.science.org/content/blog-post/dark-side-wonderful-investment-story> (Reynolds also complained his \$545k salary was insufficient).

¹³³ Pedersen, *supra* note 131.

¹³⁴ *Id.*

¹³⁵ SECURITIES AND EXCHANGE COMMISSION, Form 8-K: PixarBio Corporation, https://www.sec.gov/Archives/edgar/data/1623077/000107878216003716/f8k110216_8k.htm. See *PixarBio Corp. (PXR) Market Profile*, WALL ST. J., <https://www.wsj.com/market-data/quotes/PXR/company-people/executive-profile/147625380>.

¹³⁶ Pojasek, *supra* note 16; Lowe, *supra* note 132.

¹³⁷ *PixarBio Corporation Builds Commercialization Team Adding Regulatory Affairs, cGMP Manufacturing, Sales/Bus Dev, and Medical Affairs*, BIOSPACE (Aug. 28, 2015) <https://www.biospace.com/article/releases/pixarbio-corporation-builds-commercialization-team-adding-regulatory-affairs-cgmp-manufacturing-sales-bus-dev-and-medical-affairs/>.

Board” when he was promoted to CTO, but mentioned no specific names.¹³⁸

At the very least, it seems likely that PixarBio had a SAB in name only. Their only publicly announced SAB members became officers, calling into question whether either Dr. Langer or Dr. Khalil were truly “independent” at any time. This may appear like a conflict of interest issue, but the general lack of information on the SAB suggests that it either existed in name only or was never used. In either case, this reinforces the notion that forming an unutilized SAB does not provide protections from investor fraud. It may bolster the company’s perceived legitimacy, but doesn’t prevent the CEO from claiming the company’s drug performs miracles.

D. Cell Theranostics

Unlike like other defunct biotech firms discussed, Cell Theranostics is still operating and was established in 2021 as a subsidiary of Cell>Point L.L.C. to license out sophisticated imaging and cancer therapy treatments.¹³⁹ However, that same year, the SEC charged the company’s executives with \$10 million in fraud.¹⁴⁰ The SEC’s complaint alleges that clinical trials for the company’s lead product were suspended in 2014 and never resumed, despite efforts to address numerous technical issues.¹⁴¹ This did not stop the company leaders, Greg and Terry Colip, from allegedly telling investors that trials were ongoing and overstating the capital the company had already raised.¹⁴²

In the background, it is extremely unclear whether had Cell Theranostics or Cell>Point L.L.C. ever had a functioning SAB. The only hint that an SAB may have existed at some point was a news release from 2004, announcing that Dr. Saad Zakko joined the Cell>Point’s SAB.¹⁴³ Dr. Zakko is the director of nuclear medicine at Dubai Hospital in the United Arab Emirates, and it is unclear what connection, if any, there was to the Colorado-based biotech company.¹⁴⁴ A call to Cell Theranostics for further

¹³⁸ *PixarBio Corporation’s Dr. Jason Criscione Promoted to Chief Technology Officer*, BUS. WIRE (June 25, 2015),

<https://www.businesswire.com/news/home/20150625005194/en/PixarBio-Corporation%E2%80%99s-Dr.-Jason-Criscione-Promoted-to-Chief-Technology-Officer>.

¹³⁹ *See Our Company*, CELL THERANOSTICS, <https://celltheranostics.com/about/> (last visited Nov. 28, 2022).

¹⁴⁰ SECURITIES AND EXCHANGE COMMISSION, Litigation Release No. 25113, *SEC Charges Biotech Company and Executives in \$10 Million Offering Fraud*, June 11, 2021.

¹⁴¹ Complaint at 2, United States SEC v. Cell-Point, L.L.C., No. 21-cv-01574-PAB-KLM (D. Colo. Feb. 14, 2022).

¹⁴² Josh Sullivan, *SEC issues preliminary injunction against Colorado biotech accused of \$10M fraud*, ENDPOINT NEWS (Mar. 16, 2021), <https://endpts.com/sec-issues-preliminary-injunction-against-colorado-biotech-accused-of-10m-fraud/>.

¹⁴³ *Blog: Dr. Saad Zakko joins Scientific Advisory Board – 9|8|04*, CELL THERANOSTICS (Sept. 1, 2004), <https://celltheranostics.com/dr-saad-zakko-joins-scientific-advisory-board-9804/>.

¹⁴⁴ *Blog Dr. Saad Zakko joins Scientific Advisory Board – 9|8|04*, CELL THERANOSTICS (Sept. 1, 2004), <https://celltheranostics.com/dr-saad-zakko-joins-scientific-advisory-board-9804/>.

information on their SAB was not returned, and the voicemail message from the company's phone number appeared to reach Terry Colip's cell phone.¹⁴⁵

At the very least, it appears that Cell Theranostics has a defunct SAB. As mentioned before, the makeup of an SAB is typically touted proudly by biotech companies, raising the company's prestige and legitimacy in the eyes of the investors.¹⁴⁶ The fact it is not listed anywhere publicly, and none of the company's corporate governance documents mention a SAB is quite telling.¹⁴⁷ Like Theranos, this appears to be a company without an SAB when a crisis struck. But it had instead ignored maintaining an active SAB rather than waiting until too late to form one. Regardless of when the SAB was formed or became defunct, Cell Theranostics reinforces the pattern of a company treating the SAB as an afterthought, rather than a useful corporate governance tool.

E. Decision Diagnostics

The CEO of Decision Diagnostics Corp., Keith Berman, had an especially rough end to 2020. On December 18th of that year, the SEC announced civil charges against him and the company for making a number of false and misleading statements to investors.¹⁴⁸ On the same day, the Department of Justice announced a criminal indictment against him for a securities fraud scheme.¹⁴⁹ While Berman's 2020 woes were related to the pandemic, they were not related to the politics of wearing masks. The criminal indictment alleges that Berman claimed his company had developed a "15-second test to detect COVID-19 in a finger prick sample of blood."¹⁵⁰ After the announcement, the company's stock rose by over 1500% in value before the SEC halted trading.¹⁵¹ However, the indictment

9804/; *Editorial Team*, BRIT. J. OF HEALTHCARE AND MED. RSCH., <https://journals.scholarpublishing.org/index.php/JBEMi/about/editorialTeam> (last visited Nov. 28, 2022) (verifying Dr. Zakko's credentials).

¹⁴⁵ *Contact*, CELL THERANOSTICS, <https://celltheranostics.com/contact/> (last visited Nov. 13, 2022).

¹⁴⁶ *See* Booth, *supra* note 12.

¹⁴⁷ *Cell Theranostics, Inc. Audit Committee Charter*, CELL THERANOSTICS (Last Accessed Oct. 9, 2022), <https://celltheranostics.com/wp-content/uploads/2021/07/Cell-Theranostics-Audit-Committee.pdf>; *Cell Theranostics, Inc. Compensation Committee Charter*, CELL THERANOSTICS (Last Accessed Oct. 9, 2022), <https://celltheranostics.com/wp-content/uploads/2021/07/Cell-Theranostics-Compensation.pdf>; *Cell Theranostics, Inc. Nominating and Corporate Governance Committee Charter*, CELL THERANOSTICS (Last Accessed Oct. 9, 2022), <https://celltheranostics.com/wp-content/uploads/2021/07/Cell-Theranostics-Nom-and-Corp-Gov-Committee-Charter.pdf>.

¹⁴⁸ Press Release, Securities Exchange Commission, *SEC Charges Biotech Company and CEO with Fraud Concerning COVID-19 Blood Testing Device* (Dec. 18, 2020) <https://www.sec.gov/news/press-release/2020-327>.

¹⁴⁹ Press Release, U.S. Dep't of Just., *CEO of Medical Device Company Charged in COVID-19 Related Securities Fraud Scheme* (Dec. 18, 2020), <https://www.justice.gov/opa/pr/ceo-medical-device-company-charged-covid-19-related-securities-fraud-scheme>.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

further alleges that the advertised product was a hopeful idea meant to raise money, and was not ready for testing, manufacture, or sale.¹⁵² Once the fraud was discovered, the stock was rendered worthless and investors have also filed suit.¹⁵³

According to the company's website, Berman is the only member of the board of directors, touting "more than 35 years' experience in the healthcare field" and involvement with numerous companies involved with healthcare IT.¹⁵⁴ Mr. Berman does not appear to have a scientific or medical background, with a B.A. and M.B.A. from Indiana University.¹⁵⁵ Despite Berman's background, Decision Diagnostics appears to be a one-man show. Literally. On LinkedIn, Keith Berman is the only employee listed.¹⁵⁶ The subsidiary, PharmaTech Solutions, Inc., has a total of 8 employees on LinkedIn and sells blood-glucose testing strips for people and pets.¹⁵⁷ In fact, the only scientific expertise seemingly present in either company is Kimberly Binder, a program director for PharmaTech, who appears to have earned a B.S. in Biology from Humboldt State University and an M.B.A. from CSU Northridge.¹⁵⁸

Decision Diagnostics has every appearance of a medical device distribution company, yet duped investors into believing that it had developed a new and miraculous blood test. It seems insincere to categorize the company as truly "biotech," evidenced by the DOJ's calling it a "medical device company."¹⁵⁹ But like Puma Biotechnology, the fraud here seems clear cut. Berman allegedly advertised an interesting concept as an impending reality to raise money.¹⁶⁰ But unlike Puma, there is clearly no SAB to speak of. This would make sense if the company's primary role was as a distributor because there would be no scientific research to review. Thus, Decision Diagnostics offers two lessons for different audiences. For biotech business leaders, make sure your "nice idea" is vetted through an expert, ideally an SAB member, before announcing to investors. For investors, make sure the company claiming a biotech breakthrough is actually in biotech.

¹⁵² *Id.*

¹⁵³ Jones, *supra* note 6.

¹⁵⁴ *Company Information: Board of Directors*, DECISION DIAGNOSTICS <https://www.decisiondiagnostics.co/about.html> (last visited Nov. 28, 2022).

¹⁵⁵ *Id.*

¹⁵⁶ Decision Diagnostics Corp., LINKEDIN, <https://www.linkedin.com/company/decision-diagnostics-corp/> (last visited Sept. 24, 2022)

¹⁵⁷ PharmaTech Solutions, LINKEDIN, <https://www.linkedin.com/company/pharmatech-solutions/> (last visited Sept. 24, 2022).

¹⁵⁸ Kimberly Binder, LINKEDIN, <https://www.linkedin.com/in/kimberly-binder-943855124/> (last visited Sept. 22, 2022).

¹⁵⁹ U.S. Dep't of Just., *supra* note 149. *But see* SEC, *supra* note 148.

¹⁶⁰ Jones, *supra* note 6.

IV. SAB PATTERNS AND RECOMMENDATIONS

A. Establish and Maintain an SAB As Risk Increases

Perhaps the clearest takeaway from these stories is the importance of actually forming and maintaining a legitimate SAB when creating a biotech company. In the case of Theranos, Cell Theranostics, and Decision Diagnostics, no SAB appears to have been present while the conduct leading to fraud allegations occurred.¹⁶¹ For IRC and PixarBio, it's unclear whether an SAB was ever properly maintained.¹⁶² Simply announcing that one potentially qualified individual is now an SAB member, like Cell Theranostics and PixarBio did, does not actually create any SAB protection.¹⁶³ In this respect, the answer as to "why" an SAB didn't prevent investor fraud allegations is obvious: it didn't exist.

However, this incredibly simple answer begs a more complex question, when is the right time to form an SAB? As mentioned before, getting prestigious academics and practitioners to join an SAB costs valuable money, equity, and time.¹⁶⁴ It is likely counter-productive for a brand-new company to use its limited resources to form an SAB. Not only would the reduced available equity due to SAB member compensation potentially scare away new investors, but there is less risk of investor fraud allegations.¹⁶⁵ If the company has raised a few thousand dollars from angel investors, even if through entirely fraudulent promises, their exposure to fraud allegations is limited to that smaller pot of money and investors.¹⁶⁶ As more investments pile in, the number of possible plaintiffs increases, along with exposure to more serious legal consequences based on the size of the investments.¹⁶⁷ As investors and investments increase, an SAB becomes sensible.

But at what exact point of new investments is best to form an SAB? While there is no clear-cut answer, achieving a milestone of Series B funding may be a good starting point. The company has shown enough promise and success to attract another round of serious investment, and the

¹⁶¹ Ariel Katz, *The Theranos Fiasco Shows How Much Startup Advisory Boards Matter*, TECHCRUNCH (Oct. 10, 2021), <https://techcrunch.com/2021/10/10/the-theranos-fiasco-shows-how-much-startup-advisory-boards-matter/>.

¹⁶² *Science Advisory Board, Membership and Nomination Process*, THE ENV'T PROT. AGENCY, <https://sab.epa.gov/ords/sab/f?p=114:7:4929761631731>.

¹⁶³ *PixarBio Builds Commercialization Team Adding Regulatory Affairs, cGMP Manufacturing, Sales/Bus Dev, and Medical Affairs*, BUSINESSWIRE (Aug. 28, 2015), <https://www.businesswire.com/news/home/20150828005036/en/PixarBio-Builds-Commercialization-Team-Adding-Regulatory-Affairs-cGMP-Manufacturing-SalesBus-Dev-and-Medical-Affairs>; *Dr. Saad Zakko joins Scientific Advisory Board*, CELL THERANOSTICS (Sept. 1, 2004), <https://celltheranostics.com/dr-saad-zakko-joins-scientific-advisory-board-9804/>.

¹⁶⁴ Booth, *supra* note 12; Pojasek, *supra* note 16.

¹⁶⁵ Booth, *supra* note 12.

¹⁶⁶ See generally John D. Finnerty, *Determinants of the Settlement Amount in Securities Fraud Class Action Litigation*, 2 HASTINGS BUS. L. J. 453, 457 (2006).

¹⁶⁷ *Id.*

most attractive equity for investors has likely been divvied up. Thus, there's enough investment at stake to warrant the additional protection of an SAB, without sacrificing the limited resources available in a start-up's early stages. Plus, equity offered to SAB members won't be such a liability. Some biotech companies seem to already follow this formula.¹⁶⁸ But as uBiome and Puma demonstrate, forming an SAB at the right time may not be enough.

B. Transparency

Even though Theranos didn't have an SAB until it was too late, the company's secretive culture and tight control over information paralleled the conduct exhibited at uBiome and Puma Biotechnology.¹⁶⁹ What made these two following stories more informative however, was the fact that they both had well-staffed and functioning SABs at the time the fraud occurred.¹⁷⁰ Yet both SABs were kept in the dark regarding key information: the clinical applications being advertised and FDA disclosures.¹⁷¹ The singular control and "filtration" of information through their respective business leaders either kept the SABs in the dark, or blocked communication from lower-level employees with legitimate concerns.¹⁷²

Thus, the second takeaway from these stories is a need for transparency, both within the company and with the SAB. If employees across departments are able to communicate openly, their concerns can gain better traction and more likely avoid being "squashed," or resulting in a quick dismissal.¹⁷³ If employees are permitted to directly speak with the SAB, they also have an independent arbiter available to validate or alleviate their concerns.¹⁷⁴ The more people "in the know" regarding a potential issue at a biotech company, the less likely it is to remain a secret to investors.¹⁷⁵ This may hurt a company's prospects or stock performance

¹⁶⁸ *Orum Therapeutics Closes \$84 million in Series B Financing to Advance Novel Targeted Protein Degradator Payloads Into Clinical Trials for Cancer*, ORUM THERAPEUTICS (June 24, 2021), <https://www.orumrx.com/news/2021/6/24/orum-therapeutics-closes-84-million-series-b-financing-to-advance-novel-targeted-protein-degrader-payloads-into-clinical-trials-for-cancer-1>; *Orum Therapeutics Announces Formation of Scientific Advisory Board*, BUSINESS WIRE (Apr. 04, 2022), <https://www.businesswire.com/news/home/20220404005350/en/>.

¹⁶⁹ The Journal, *supra* note 61; Transcript of Record at 20, 23, *Hsu v. Puma Biotechnology, Inc.*, No. 8:15-cv-00865 (C.D. Cal. June 3, 2015).

¹⁷⁰ Scientific Advisory Board of Puma Biotechnology, Inc., PUMA BIOTECHNOLOGY, https://www.pumabiotechnology.com/docs/corpgov/cg2019/pdf/Scientific_Advisory_Board.pdf (last visited Sept. 30, 2022); The Journal, *supra* note 61.

¹⁷¹ The Journal, *supra* note 61; Transcript of Record at 20, 23, *Hsu v. Puma Biotechnology, Inc.*, No. 8:15-cv-00865.

¹⁷² The Journal, *supra* note 61; Transcript of Record at 20, 23, *Hsu v. Puma Biotechnology, Inc.*, No. 8:15-cv-00865.

¹⁷³ See John Carreyrou, *Book Excerpt: What Happened When Theranos Exec Confronted Elizabeth Holmes About Her Lack of Ethics*, KQED (May 31, 2018), <https://www.kqed.org/futureofyou/442098/book-excerpt-one-execs-tumultuous-last-day-at-theranos>.

¹⁷⁴ See Booth, *supra* note 12.

¹⁷⁵ See The Journal, *supra* note 61.

in the short run, but can build confidence with investors over time and prevent fraud from spiraling into a lawsuit.

C. Give the Shield “Teeth”

Lastly, these stories largely portray SABs as “toothless” advisors, meaning that they have no real power over the decisions or conduct of the company. In theory, a well-run SAB could still be powerless to prevent business leaders from committing investor fraud. If they felt morally obligated, their only option may be to “go public” with the information, as was the case the independent researchers for IRC.¹⁷⁶ However, such a drastic move would likely sever the ability of SAB members to provide candid advice.¹⁷⁷ Business leaders may even be less likely to form an SAB if they knew rejecting a recommendation meant risking a public embarrassment.

Instead, SABs should have an internal mechanism to provide a real “check” against reckless business leaders hellbent on committing investor fraud. For example, biotech companies could incorporate the SAB into their corporate governance, allowing for SAB members to request a board of directors meeting to discuss their concerns if they unanimously opposed a specific business strategy or practice. The CEO would be less likely to shrug off their advice, knowing that a particularly egregious departure would result in answering to the board.

V. CONCLUSION

At best, SABs are an under-utilized corporate governance tool. At worst, they have been completely forgotten among many biotech entrepreneurs as a way to protect themselves from becoming a legal target for investor fraud. Instead, SABs are frequently treated as a public-relations afterthought. The SAB should not be an addendum. It is a ready-made shield against disgruntled investors and to protect a company’s scientific integrity. But, as with any tool, it is only as good as its users.

¹⁷⁶ See Haack, *supra* note 106, at 57.

¹⁷⁷ See generally *Scientific Advisory Committees*, UNION OF CONCERNED SCIENTISTS (June 13, 2019), <https://www.ucsusa.org/resources/scientific-advisory-committees#:~:text=It%27s%20important%20to%20understand%20that,that%20advice%20in%20making%20decisions>.