MiMedx – filling in the blanks.

More ties to Forest Park, active breach of federal sales regulations, knockback of "independent" research and the dead-on-arrival of international expansion.

The fraud at MiMedx continues to unravel as the company announced it would have to restate more than half a decade's worth of financials, doctors receiving bribes from MiMedx and that its short selling commentary cannot be relied upon. Viceroy have identified further issues with the company including:

- The announcement of MiMedx's international expansion was a sad attempt at distracting investors from the Company's compliance updates.
  - In the UK, the technology commentary from the NHS appears very skeptical as to the efficiency and economic viability of MiMedx's EpiFix product compared to existing solutions. EpiFix has been available in the UK for 2 years as of January 2018, and the product was only stocked in 1 National Health Service ("NHS") facility.
  - Viceroy have begun contacting international regulators to present evidence.
- A major stumbling block to regulatory approval, as indicated by UK regulators, is the lack of independent research into MiMedx products' efficacy and significant difference between company funded/sponsored reports and limited independent patient data.
- Viceroy have uncovered an AmnioFix study conducted by Forest Park Medical Center employee, John Dulemba, and MiMedx consultant and former Matria healthcare Director of Clinical Research, Niki Istwan.
  - The study has no disclosures on compensation or relationships with MiMedx.
  - Istwan appears on multiple MiMedx studies sometimes as a MiMedx consultant and other times as an "independent". We believe this obfuscation of relationships to the company is intentional and used by MiMedx to create an illusion of independence. MiMedx does not report payments to Doctors despite the legal requirements.[1]
- One of three individuals recently indicted for fraudulently accepting payments from MiMedx was *also* part of a clinical study into MiMedx products. The implication that MiMedx clinical research is directly influenced by the Company is likely to deter international approval altogether. More so for paying bribes to Doctors[2]. MiMedx denied paying bribes or inducements in legal filings and illegal short selling commentary, but the Grand Jury disagrees.
- **MiMedx is in breach of federal procurement regulations (FAR/DFAR)** due to the conditioning of settlement agreements and litigation settlements with former employees and whistleblowers on a requirement for **withdrawal of complaints to, and prohibition of communication with, regulatory authorities**. We have reported this to the relevant authorities and believe their findings will corroborate our own.

For further background on this issue, please refer to Viceroy's MiMedx Greatest Hits report:

https://viceroyresearch.org/2018/05/11/viceroys-mimedx-greatest-hits/

[1] https://www.wsj.com/articles/mimedx-fast-growing-developer-of-tissue-graft-products-didnt-report-payments-to-doctors-1519300800

[2] http://uk.businessinsider.com/veterans-affairs-employees-indicted-for-taking-bribes-from-mimedx-2018-5

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The NHS Flop and slew of questionable trials

Contrary to company statements, MiMedx's recently announced "international expansion" [3] is neither advanced nor new. While MiMedx's hype machine was present on the release of previous studies, it would appear the company failed to inform investors of the UK's National Institute of Health and Care Excellence's ("NICE") MedTech innovation briefing on EpiFix. The purpose of NICE MedTech innovation briefings is to support the NHS and other government authorities in deciding whether to use new medical or diagnostic technology. The full MedTech innovation briefing is available at:

https://www.nice.org.uk/advice/mib139/chapter/Summary

A MedTech innovation briefing by the UK's National Institute of Health and Care Excellence's shows that while EpiFix was granted a Human Tissue Authority ("HTA") license[4] in February 2012 and was launched in January 2016, as of January 2018 only **one NHS facility used the product**.

> **Resource consequences**
>
> EpiFix would be a significant additional cost to standard care. If treatment resulted in higher healing rates, the additional costs could be offset by reduced use of dressings and chronic wound-care services and by avoiding future complications such as lower limb amputation. Staff may need training on the correct application of EpiFix. EpiFix is currently used in 1 NHS wound-care centre.

Figure 1 Extract of EpiFix's NICE MedTech innovation briefing5

Nearly six years after being granted an HTA license and two and a half years after launching EpiFix in the UK, MiMedx conveniently announced their international strategy and expansion in the UK on June 7, 2018. Why? Their entrance to the market was essentially dead-on-arrival.

> NICE advice also states that the least costly dressings that meet the required clinical performance characteristics should be used, because there is not enough evidence to determine whether advanced dressings (such as hydrocolloids, alginates and hydrofibre dressings) are more clinically effective than conventional dressings.

Figure 2 Extract of EpiFix's NICE MedTech innovation briefing

In essence, the exorbitant cost of MiMedx's products compared to incumbent solutions appears to have stopped the company's UK expansion in its tracks.

Of greatest relevance to this report and the MiMedx story at large are the NICE's consultants' views on the available literature regarding MiMedx products:

> support these claims. One commentator noted that there was a high level of overlap and potential for reporting bias in the current studies and that more, independent studies would be needed to confirm these benefits. The third specialist commentator stated that there was not enough

Also relevant to greater story of the MiMedx's misdeeds is that NICE had difficulty gauging:

1. The economic benefits of EpiFix compared to incumbent treatments
2. The medical benefits of EpiFix compared incumbent treatments, citing the innovation as "novel"
3. The impartiality and opaque reporting of the existing literature on EpiFix

[3] https://www.prnewswire.com/news-releases/mimedx-announces-executive-to-lead-its-international-operations-and-provides-update-on-companys-international-progress-300661471.html
[4] HTA license #22,512
[5] https://www.nice.org.uk/advice/mib139/chapter/Summary

- **Key uncertainties** around the evidence or technology are that all studies took place in the US and so comparisons and patient selection may not be generalisable to the NHS. In particular, there are no comparisons of EpiFix with standard NHS care for any indication. Two of the 5 studies included were written by the same group of authors (Zelen et al.) and 4 studies were funded by the company. Four other studies are ongoing, and 5 studies have been completed but not published.

Figure 3 Extract of EpiFix's NICE MedTech innovation briefing

Of the 5 studies reviewed by NICE in their literature review, 4 were sponsored and funded by MiMedx. NICE also note that there are a further 5 completed studies "with no results available". Why?

The sole independent study is a retrospective analysis of 218 patients comparing EpiFix to bio-engineered living cellular constructs ("BLCCs") which we will refer to as the **Kirsner Study**. While the Kirsner Study has significant ties to MiMedx competitor Organogenesis, it is telling that the data sourced from healthcare information aggregator Net Health disagrees firmly with the MiMedx sponsored and funded studies.

In essence, EpiFix's performance during MiMedx-sponsored and funded studies **differed significantly from the data collated by Net Health in time-to-closure and healing rates**.

In that analysis, Zelen et al. report 85% of dHACM patients achieved complete healing after 4 weeks and that 95% of dHACM patients achieved complete healing after 6 weeks.[14] The median time to healing with dHACM was reported to be 13 days. Such healing rates are dramatically different than any other product in the published wound healing literature.[24] The current study, which examined 225 wounds, found that only 17% of BLCC-treated wounds and 9% of dHACM-treated wounds were healed by week 6 (data not shown), with a median time to healing of 93 and 182 days, respectively.

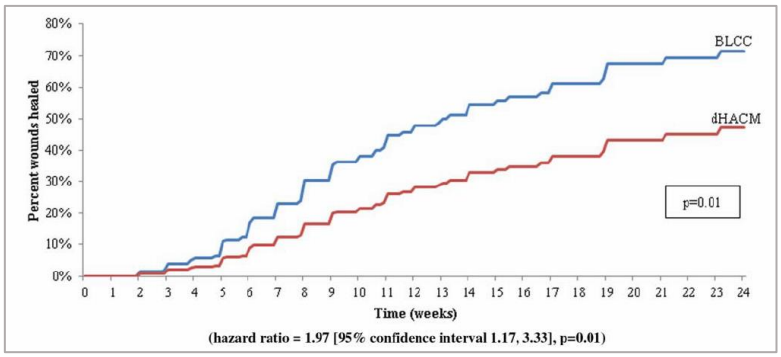


Figure 4 & 5 Extract of "Comparative effectiveness of a bioengineered living cellular construct vs. a dehydrated human amniotic membrane allograft for the treatment of diabetic foot ulcers in a real-world setting"[6]

A thorough discussion on the effects of sponsorship and funding on research integrity is beyond the scope of this report and Viceroy's remit, however we point out that MiMedx-funded studies conducted by Dr Thomas Serena, a MiMedx consultant, appear to have adulterated inclusion and does not include recognized endpoints FDA.

[6] https://onlinelibrary.wiley.com/doi/epdf/10.1111/wrr.12332

Dr Serena publicly states that he selectively chooses patients for a trial to guarantee "success", which is, frankly, ridiculous. Dr Serena has received criticism from peers, including the HHS wound care review lead at Johns Hopkins Bayview Medical Center, in this regard:

> Thomas Serena, one of the most prolific researchers of wound-healing products, said he tries to pick the healthiest patients for inclusion in studies, limiting him to a pool of about 10 percent of his patient population.
>
> "We design it so everyone in the trial has a good chance of healing," he said.
>
> "If it works, like, 80 or 90 percent of the time, that's because I pick those patients," said Serena, who has received funding from manufacturers.
>
> But critics say the approach makes it more difficult to know what works on the sickest patients in need of the most help.
>
> Gerald Lazarus, a dermatologist who led the HHS review as then-director of Johns Hopkins Bayview Medical Center wound care clinic, said Serena's assertion is "misleading. That's not a legitimate way to conduct research." He added that singling out only healthy patients skews the results.
>
> The emphasis on healthier patients in clinical trials also creates unrealistic expectations for insurers, said Fife.
>
> "The expensive products ... brought to market are then not covered by payers for use in sick patients, based on the irrefutable but Kafka-esque logic that we don't know if they work in sick people," she said.

Figure 6 "When Wounds Won't Heal, Therapies Spread – To The Tune Of $5 Billion" – Kaiser Health News[7]

Dr Serena's study, titled "A multicenter, randomized, controlled clinical trial evaluating the use of dehydrated human amnion/chorion membrane allografts and multilayer compression therapy vs. multilayer compression therapy alone in the treatment of venous leg ulcers", has also drawn severe criticisms from peers.

A letter to the editor by wound care researchers, who are also employed by Smith and Nephew, highlight several "problems" in Dr Serena's trial, including:

- Selective, "easy to heal" wounds for trials were not representative of the chronic leg ulcers patient population
- Inconsistency in minimum eligible ulcer size used in the study and published on www.clinicaltrials.gov. In fact, the average ulcer size in the study was >10% smaller than the minimum size specified in the clinical study database
- The endpoint selected by Dr Serena is not recognized by the FDA, as it is inconclusive. Research shows endpoint used by Dr Serena is only valid 70% of the time, significantly reducing the end result.
- Archaic wound-measuring tools should have been forgone for greater accuracy (i.e. MiMedx simply used length x width, measured with a ruler)

This critical piece can be accessed here: https://onlinelibrary.wiley.com/doi/full/10.1111/wrr.12257

The implication that MiMedx manipulates study results further reinforces the statements to Viceroy by several former employees of a culture of kickbacks and bribes persisted at MiMedx with the full knowledge and endorsement of the company's executive management.

To conclude, MiMedx's attempt to showcase an international expansion was petty and insulting to stakeholders given the much more pertinent news.

[7] https://khn.org/news/when-wounds-wont-heal-therapies-spread-to-the-tune-of-5-billion/

Further links to Forest Park Medical Center

The lack of impartial research into MiMedx products runs through its entire catalogue. Studies either sponsored or funded by MiMedx tend to have positive conclusions. However, sometimes these connections are not disclosed, and Viceroy believes this is done intentionally in order to deceive medical professionals boost sales of MiMedx product and influence approvals by regulatory bodies.

Of note is a study of MiMedx's AmnioFix product in gynecological surgery recovery:

Evaluation of Dehydrated Human Amnion/Chorion Membrane as an Adhesion Barrier in Women Undergoing Robotic Laparoscopy

John Dulemba, Pezhman Mirzakhani, and Niki B Istwan

Figure 7 Extract of "Evaluation of Dehydrated Human Amnion/Chorion Membrane as an Adhesion Barrier in Women Undergoing Robotic Laparoscopy" [8]

Readers who view this report online will note that there is no mention as to whether the company sponsored or funded the study. The links are there, though…

First author: John Dulemba of Forest Park Medical Center

Viceroy have previously reported on significant relationships between MiMedx, its distributors, and the fraud at Forest Park Medical Center, a private hospital in Dallas where 21 physicians were indicted in 2016 for accepting bribes, kickbacks and other inducements. MiMedx was a registered creditor here and proven supplier.

Department of Justice

U.S. Attorney's Office

Northern District of Texas

SHARE

FOR IMMEDIATE RELEASE — Thursday, December 1, 2016

Executives, Surgeons, Physicians, and Others Affiliated with Forest Park Medical Center (FPMC) in Dallas Indicted in Massive Conspiracy

FPMC Paid Approximately $40 Million in Bribes and Kickbacks in Exchange for Patient Referrals

DALLAS – Founders and investors of the physician-owned Forest Park Medical Center (FPMC) in Dallas, other executives at the hospital, and physicians, surgeons, and others affiliated with the hospital, have been charged in a federal indictment, returned by a grand jury in Dallas last month and unsealed today, with various felony offenses stemming from their payment and/or receipt of approximately $40 million in bribes and kickbacks for referring certain patients to FPMC. The announcement was made this afternoon by U.S. Attorney John Parker of the Northern District of Texas.

FPMC was an out-of-network hospital. According to the indictment, the referred patients were primarily ones with high reimbursing out-of-network private insurance benefits or benefits under certain federally-funded programs. FPMC's owners, managers, and employees also attempted to sell patients with lower reimbursing insurance coverage, namely unwitting Medicare and Medicaid beneficiaries, to other facilities in exchange for cash. As a result of the bribes, kickbacks, and other inducements, from 2009 to 2013, FPMC billed such patients' insurance plans and programs well over half of a billion dollars and collected over $200 million in paid claims.

Figure 8 DOJ Press Release relating to Forest Park Medical Center[9]

[8] https://www.omicsonline.org/open-access/evaluation-of-dehydrated-human-amnionchorion-membrane-as-an-adhesion-barrier-in-women-undergoing-robotic-laparoscopy-2161-0932-1000405.pdf

[9] https://www.justice.gov/usao-ndtx/pr/executives-surgeons-physicians-and-others-affiliated-forest-park-medical-center-fpmc

The first author of the above study, Dr John Dulemba, is an employee at Forest Park Medical Center. His name on the list of creditors from the center's chapter 11 bankruptcy creditor's list[10], his appearance in a YouTube video on Forest Park's channel and industry documents indicate his presence at Forest Park during the time the fraud took place:

Dr. John Dulemba, gynecological surgery
Forest park Medical Center (Frisco, USA)
"Working with both robots makes it easier to operate since I can control the camera, the instruments and the movements of the uterus positioner. **VIKY provides a perfect view of the patient's uterus. The uterus is grasped firmly and proper upward traction is maintained throughout the procedure.** The system's voice control means I can stay focused and work steadily, as I can position the uterus exactly how I want it, without having to get up from the console or continually ask my assistant to readjust the position."

Figures 9 & 10 Screen-capture of Forest Park YouTube video[11] & *Extract of Endocontrol Brochure*[12]

MiMedx denies any association with the indicted Forest Park Medical Center individuals and assert their relationship ended with those involved. Indeed, in their now-retracted and possible criminal short selling commentary MiMedx attempted to distance themselves from the facility:

MiMedx:
This is yet one more pure fabrication from Viceroy. First of all, the relationship between CPM and MiMedx ended in 2015, with our last shipment in July of 2015. The end of this contract had nothing to do with Forest Park. According to available records, Forest Park declared bankruptcy in late 2015, and the Attorney General's indictments of the physician owners occurred in December of 2016, over a year after the CPM/MiMedx contract ended. This is a rather absurd example of the lengths Viceroy will go to in order to create uncertainty or attempt a correlation where one simply cannot exist. How does Viceroy believe MiMedx could predict the future bankruptcy of Forest Park Medical? The MiMedx ability to predict the future through a crystal ball is as believable as these fabricated channel stuffing claims.

MiMedx:
This is FALSE. MiMedx does not have business relationships with the indicted Forest Park individuals. As mentioned previously, MiMedx does not control to whom our distributors sell products. If one of these individuals or the companies purchase MiMedx product from a distributor, it does not create a direct business relationship with MiMedx.

Figures 11 & 12 Extracts of MiMedx short selling commentary – Oct 17, 2017

However, **Viceroy have also previously detailed MiMedx's dealings with indicted Forest Park individual Israel Ortiz[13].** We believe the authorities investigating MiMedx are already looking into the company's connection to the fraud that took place at Forest Park. MiMedx deny the association, but receipts show otherwise.

Third author: Niki B Istwan, aka "the Fixer"

The third author of the afore-mentioned study, Niki B Istwan has a direct connection to MiMedx and the company formerly headed by MiMedx CEO Parker Petit, Matria Healthcare.

Niki B Istwan is the former Director of Clinical Research at Matria Healthcare which Petit founded and works as a consultant for MiMedx. Istwan also operates her own consultancy Istwan Consulting Services.

[10] http://trace.lib.utk.edu/assets/Kuney/2016_FOREST-PARK/Case_15-41684%20Application%20for%20Compensation_1_DTBA%20Doc%20No_387.pdf
[11] https://www.youtube.com/watch?v=Bib2cZJOHYs
[12] https://normedi.com/wp-content/uploads/2017/05/1704_Lap_Robotic_Viky_Broschyr.pdf
[13] https://viceroyresearch.org/2018/05/11/viceroys-mimedx-greatest-hits/

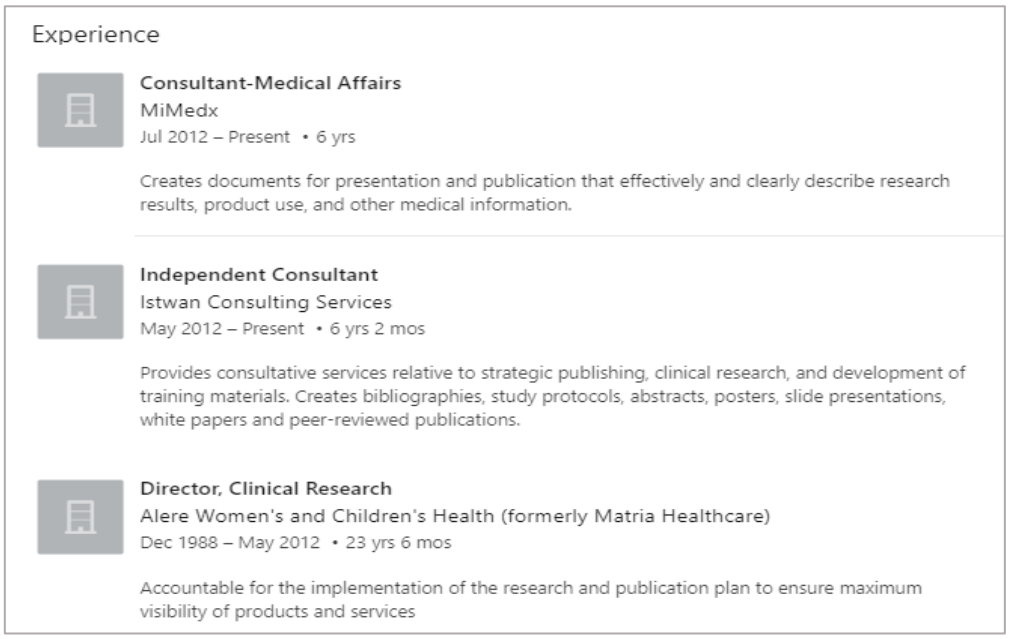
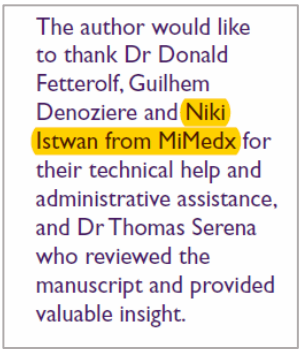
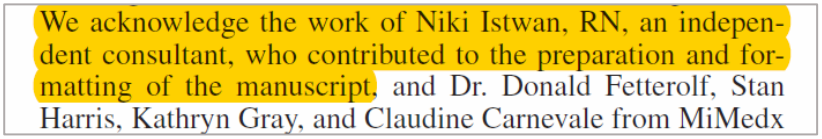
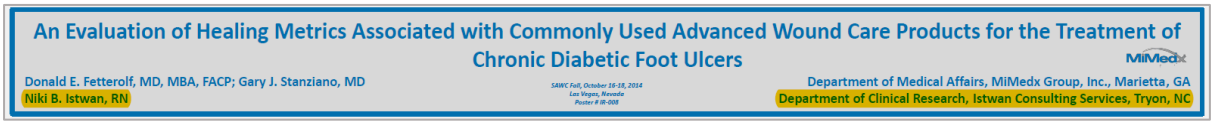


Figure 13 Extract of Niki Istwan's LinkedIn.com profile[14]

Indeed, Istwan's work with MiMedx has been prolific appearing on several other publications and studies.







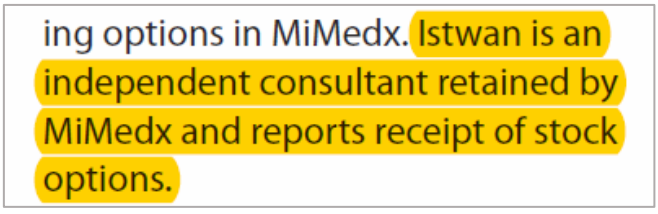


Figure 14 Extracts of various publications related to MiMedx products[15,16,17,18]

[14] https://www.linkedin.com/in/niki-istwan-54471a20/
[15] https://mimedx.com/wp-content/uploads/2018/04/An-evaluation-of-dehydrated-human-amniotic-membrane-allografts-in-patients-with-DFUs.pdf
[16] https://mimedx.com/wp-content/uploads/2018/05/23-EP291.001-Fetterolf-SAWC-Fall-2014-Poster.pdf
[17] https://mimedx.com/wp-content/uploads/2018/04/A-Multi-center-Randomized-Controlled-Clinical-Trial-Evaluating-the-Use-of-Dehydrated-Human.pdf
[18] https://mimedx.com/wp-content/uploads/2018/04/An-Evaluation-of-Healing-Metrics-Associated-With-Commonly-Used-Advanced-Wound-Care-Products-For-the-Treatment-of-Chronic-Diabetic-Foot-Ulcers.pdf

Istwan is the only employee we could find of **Istwan Consulting Services, and the company has no presence outside of MiMedx-related releases**. Taken together with Istwan's previous involvement with a company headed by MiMedx CEO Parker "Pete" Petit and it is clear that Istwan's involvement in any study is only to give it the veneer of independence.

No doubt readers will understand NICE's issues with gauging the effectiveness of MiMedx's products when almost all literature on the subject has ties either direct or indirect to the company. To say nothing of indicted individuals involved in MiMedx studies…

Indictment of VA employees involved in MiMedx studies

Those following the MiMedx story will be fully aware of the recent formal accusation of three healthcare providers for **receiving bribes from MiMedx** in exchange for speaking engagements and excessive use of MiMedx products. **Remember Parker Petit and MiMedx denied the payment of *any* bribes or inducements in Court Documents. Now a Grand Jury does is unconvinced.**

HEALTH NEWS MAY 10, 2018 / 4:37 AM / A MONTH AGO

U.S. indicts three veterans healthcare providers over MiMedx payments

Donna Becker, 54, Dr. Marcela Dolores Farrer, 53, and Carol Guardiola, 65, were accused in an indictment filed in federal court in Greenville, South Carolina, on Tuesday of improperly taking thousands of dollars from MiMedx.

Figures 15 & 16 Extracts of Reuters article: "U.S. indicts three veterans healthcare providers over MiMedx payments"[19]

One of those indicted, Dolores Farer was involved with an EpiFix clinical trial publicized by MiMedx as a triumph:

The paper entitled ***"A Multicenter Randomized Controlled Trial Evaluating the Efficacy of Dehydrated Human Amnion/Chorion Membrane (EpiFix) Allograft for the Treatment of Venous Leg Ulcers,"*** was authored by Christian Bianchi, MD, FACS; Shawn Cazzell, DPM, FACFAS; Dean Vayser, DPM, FACFAS; Alexander M. Reyzelman, DPM, FACFAS; Hasan Doslouglu, MD, FACS; Gregory Tovmassian, DPM; and the EpiFix VLU Study Group of Delores Farrer, DPM, MBA, CWS; Elisa Taffe, MD; Lacey Loveland, DPM; David O'Connor, MD; Marc D. Baer, DPM, FACFAS; and Sara Dahle, DPM, MPH.

Figures 17 & 18 Extracts of Reuters article: "U.S. indicts three veterans' healthcare providers over MiMedx payments"[20]

As Viceroy have previously detailed in our "MiMedx: Greatest Hits" report, the facility at which all three indicted officials were operating played host to at least two of MiMedx's clinical trials. Two of the indicted officials including Farrer had spoken for MiMedx on the efficacy of their products.

MiMedx management have maintained an amateurish attempt to distance themselves from the Forest Park Medical Center by throwing their distributors under the bus. This is despite Viceroy having identified indicted Forest Park individuals holding and using MiMedx product.

[19] https://www.reuters.com/article/us-mimedx-group-court/u-s-indicts-three-veterans-healthcare-providers-over-mimedx-payments-idUSKBN1IA312

[20] https://www.reuters.com/article/us-mimedx-group-court/u-s-indicts-three-veterans-healthcare-providers-over-mimedx-payments-idUSKBN1IA312

MiMedx in breach of their FAR & DFARs federal regulations?

For those unfamiliar with the MiMedx story, the General Services Administration ("GSA") provides centralized procurement for the United States federal government. The rules governing this procurement system are Federal Acquisition Regulations and Defense Federal Acquisition Regulations (together, FAR & DFARs).

Viceroy have previously covered issues with MiMedx's Federal Acquisition Regulation and Defense Federal Acquisition Regulation FAR & DFARs forms. The company's relationship to its previous middleman AvKare has also come under scrutiny as filings show that MiMedx essentially used AvKare's FSS to sell to the government.

Our analysis shows that **MiMedx is in breach of FAR & DFARs regulations due to its confidentiality and severance agreements, as well as the conditions of its litigation settlement with former employees, which prevents and discourages the reporting of fraud to authorities**. Those following the fraud will note that MiMedx instructed lawyers to request the retraction of regulatory reports of fraud from Former Employees[21]. Remember this request[22].

Additionally, your clients would have to cooperate with us by providing all documentation we seek as well as sworn, oral testimony. We would need this evidence to pursue the other litigations of which you are aware.

Lastly, we would need you to contact any and all governmental authorities you previously have reached out to and (a) withdraw previously-made complaints and (b) provide a statement that your clients' initial complaint was frivolous based on facts of which you are currently aware.

Figure 19 MiMedx lawyers request the retraction of regulatory statements.

FAR & DFAR regulations and criteria must be met by federal suppliers, including "FAR 52.203-18 **Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation":**

FAR 52.203-18 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation (JAN 2017)

As prescribed in 3.909â€"3(a), insert the following provision: Prohibition on Contracting With Entities That Require Certain Internal Confidentiality Agreements or Statements-Representation (JAN 2017)

(a) Definition.

Internal confidentiality agreement or statement, subcontract, and subcontractor, as used in this provision, are defined in the clause at 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

(b) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(c) The prohibition in paragraph (b) of this provision does not contravene requirements applicable to Standard Form 312, (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(d) Representation. By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(End of Provision)

Figure 20 FAR 52.203-18 [23]

Recent court documents show that MiMedx's severance and confidentiality agreements violate this condition, well-documented demands to whistleblowers to withdraw claims made to governmental authorities.

[21] https://viceroyresearch.files.wordpress.com/2017/11/part-17-sec-submission.pdf
[22] Case: 1:16-cv-11715 Document #: 112 Filed: 11/03/17 Page 115 of 165 PageID #:2181
[23] https://www.lexology.com/library/detail.aspx?g=b2c12129-f8dc-4e8b-9e25-f55613ee315f

118. On April 3, 2017, MiMedx's counsel, Joseph D. Wargo of Wargo French LLP sent Messrs. Kruchoski and Tornquist's counsel an e-mail regarding the potential settlement of the parties' civil litigation. Mr. Wargo stated that "we continue to be hampered by . . . you reaching out to government authorities concerning your clients' claims which we consider to be frivolous." (Exhibit 15). Mr. Wargo, apparently acting on behalf of MiMedx, conditioned settling the civil litigation, including its claims against Messrs. Kruchoski and Tornquist, on their counsel "contact[ing] any and all governmental authorities to whom you have previously reached out to and (a) withdraw[ing] previously-made complaints made and (2) provid[ing] a statement that that your clients' initial complaint was frivolous based on facts of which you are currently aware." (*Id.*).

Figure 21 Extract from Fox v MiMedx[24]

This is a widespread practice at MiMedx and is consistent throughout the whistleblower legal documents wherein MiMedx consistently conditions severance pay and litigation settlement on the silence of individuals.

receipt of severance pay and benefits was conditioned on Loch not taking any action that would be adverse to the Company's interests, including disclosing to any person sensitive or secret information acquired in connection with her employment. (*Id.*) MiMedx made no exception for communicating civil or criminal violations to law enforcement agencies, including the SEC. (*Id.*) On information and belief, MiMedx has issued the same or similar agreements to other former employees. Such agreements are void for public policy and violate federal law or regulation. *See, e.g.*, 17 C.F.R. § 240.21F-17.

Figure 22 Extract from Fox v MiMedx

Viceroy have reported extensively on the illegality of this practice, to say nothing of the breach of a federal regulations. We have informed the relevant authorities of this breach of regulations on the part of the company.

Viceroy believe it is a matter of time indictments of Professionals receiving bribes processes to those paying said bribes, at which point **MiMedx will also failed to update courts across the country of MiMedx being implicated in paying bribes**. FAR DFARS certification requires this disclosure from principals. Importantly, MiMedx already employs staff incestuously from companies previously named in DOJ cases for paying inducements. Viceroy believe MiMedx is already in breach of this regulation.

The obvious implication, of course, is that MiMedx will lose sales access to Federal Facilities, wiping out any federal revenue possibilities for years ahead (not to mention associated fines).

the award of contracts by any Federal agency;
(B) Have [ ] Have not [X] , within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) contract or subcontract; violation of Federal or State antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property(if offeror checks "have", the offeror shall also see 52.209-7, if included in this solicitation);
(C) Are [ ] Are not [X] presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision.
(D) Have [ ] Have not [X] , within a three-year period preceding this offer, been notified of any delinquent

Figure 23 FDAR Requirements for paying bribes

[24] Case: 1:16-cv-11715

Conclusion

NICE's MedTech innovation briefing highlights the issues we believe MiMedx products will face overseas, and further doubt that international regulatory authorities will accept the solutions. A lack of independent clinical research on their products efficacy coupled with the scandal currently surrounding the company are likely to deter regulatory approval.

Accordingly, we believe that MiMedx's announcement of an international focus is nothing but window dressing to distract from the required restatement of more than half a decade's worth of financial data. In addition to this, MiMedx's "short selling commentary" has been retracted from its website and in a recent court filing, claimed these cannot be relied upon.

> [1] Since Petit's deposition, MiMedx has removed its legal commentary from its website, stated that these and other previous statements cannot be relied upon, and announced that it must restate roughly six years' of financial statements due to investigation results focused on accounting treatment afforded to "sales and distribution practices" for two unnamed distributors for which "certain implicit arrangements modified the explicit terms of the contracts, impacting revenue recognition during specified periods." MiMedx Group, Inc. 8-K (June 6, 2018). *Cf. generally* Second Am. Counterclaim (ECF No. 147) (recounting MiMedx's fraudulent revenue recognition scheme in both private and public sales channels and MiMedx's failure to disclose agreements with distributors that differed from the explicit terms of the contract). MiMedx further disclosed that the forthcoming Restatement will have a "material impact" on its prior financial statements.

Additionally, MiMedx's actions against whistleblowers and former employees appear to be clearly in breach of federal supply regulation, which will prohibit them from selling to government entites. We have reported this to the relevant authorities.

Viceroy reiterate our belief that MiMedx is uninvestable and believe that the fraud at the company will continue to unravel at a fast pace.