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.

▪ 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.

▪ 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/viceroy-s-mimedx-greatest-hits/

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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.

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.

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:

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

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4 HTA license #22,512
5 https://www.nice.org.uk/advice/mib139/chapter/Summary
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.

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.

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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.

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.

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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:


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.

![Figure 8 DOJ Press Release relating to Forest Park Medical Center](https://www.justice.gov/usao-ndtx/pr/executives-surgeons-physicians-and-others-affiliated-forest-park-medical-center-fpmc)

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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\textsuperscript{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:

\begin{figure}[h]
\centering
\includegraphics[width=0.8\textwidth]{figures.png}
\caption{Screen-capture of Forest Park YouTube video\textsuperscript{11} \\& Extract of Endocontrol Brochure\textsuperscript{12}}
\end{figure}

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:

\begin{quote}
\textbf{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.
\end{quote}

\begin{quote}
\textbf{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 company purchase MiMedx product from a distributor, it does not create a direct business relationship with MiMedx.
\end{quote}

\begin{figure}[h]
\centering
\includegraphics[width=0.8\textwidth]{figures.png}
\caption{Figures 11 & 12 Extracts of MiMedx short selling commentary – Oct 17, 2017}
\end{figure}

However, Viceroy have also previously detailed MiMedx’s dealings with indicted Forest Park individual Israel Ortiz\textsuperscript{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.

\textbf{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.

\textsuperscript{10} http://trace.lib.utk.edu/assets/Kuney/2016_FOREST-PARK/Case_15-41684%20Application%20for%20Compensation_1_DTBA%20Doc%20No_387.pdf
\textsuperscript{11} https://www.youtube.com/watch?v=8ib2zJOHYs
\textsuperscript{12} https://normedi.com/wp-content/uploads/2017/05/1704_Lap_Robotic_Viky_Broschyr.pdf
\textsuperscript{13} https://viceroyresearch.org/2018/05/11/viceroys-mimedx-greatest-hits/
Indeed, Istwan’s work with MiMedx has been prolific appearing on several other publications and studies.

We acknowledge the work of Niki Istwan, RN, an independent consultant, who contributed to the preparation and formatting of the manuscript, and Dr. Donald Fetterolf, Stan Harris, Kathryn Gray, and Claudine Carnevale from MiMedx.

Istwan from MiMedx for their technical help and administrative assistance, and Dr. Thomas Serena who reviewed the manuscript and provided valuable insight.

Istwan is an independent consultant retained by MiMedx and reports receipt of stock options.

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14 https://www.linkedin.com/in/niki-istwan-54471a20/
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.

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

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.

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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 Employees21. Remember this request22.

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)](image)

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.

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
On April 3, 2017, MiMedx’s counsel, Joseph D. Wargo of Wargo French LLP sent Messrs. Kruchoski and Tomquist’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 Tomquist, 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.).

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.

Viceroy have reported extensively on the illegality of this practice, to say nothing of the breach of a federal regulation. 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).
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.

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 entities. 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.

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