



At What Point Is MNK Selective Disclosure Complete Fraud?

Company hides clinical results from investing public.

Caught in the crosshairs of drug pricing scandals and the opioid epidemic, Mallinckrodt has found itself the subject of not one but two 60 Minutes exposes over the past six months. This is a feat so dubious that the only name mentioned more frequently is Kabul, Afghanistan.

<https://www.cbsnews.com/news/the-problem-with-prescription-drug-prices/>

https://www.cbs.com/shows/60_minutes/video/xAy5pd4YKURdlGgc64_LOWzsUwhwYgni/jailed-doctor-who-made-over-6-000-a-day-pushing-opioids-shows-no-remorse/

However, the controversy should now come to an end.

There was never a debate whether Mallinckrodt's overpriced H.P. Acthar Gel accounted for a majority of the Company's earnings. This was something recognized by both bulls and bears.

The key debate was whether the Company could stabilize declines in Acthar and produce data to support the drug's efficacy.

Now, here are the results of a robust study published in this months American Society of Nephrology.

“The trial was stopped at a preplanned interim analysis after enrollment of 31 participants because of a lack of discernible treatment efficacy.”

In other words, the data was so bad there was no reason to continue the study.

What makes the results of this particular trial so important to the whole Mallinckrodt story is that this is the first multi-centered randomized trial conducted by established institutions actually funded and supported by Mallinckrodt.

What is beyond amazing is this morning MNK dismissed the results of the study because they had no formal input on design of the study. In other words MNK is saying – "It was independent and we only want data that we can manipulate."

Citron Research was a major critic of the Company's prior studies and even offered \$1 million for the Company to do a proper test of the drug. Our thesis was that Mallinckrodt was refusing to run real trials because they knew the drug was useless.

<https://www.thestreet.com/story/13575495/1/andrew-left-challenges-mallinckrodt-to-do-proper-study-of-its-main-drug.html>

When is Selective Disclosure Stock Fraud?

We think Mallinckrodt is trying to hide the truth. We would love for MNK to sue us so we could subpoena the emails around its communication regarding disclosure.

The Company has not released the results of the above study on its site, yet it put out a release for every other Phase 1 or enrollment. Would MNK have agreed with and disclosed the study if it had positive results? Our readers can probably guess the answer.

<http://www.mallinckrodt.com/about/news-and-media/>

Bribes and Payoffs are not Research!!

This morning in its response to Citron, MNK released this line,

“Mallinckrodt has invested more than \$400 million in the drug since 2014”

http://phx.corporate-ir.net/phoenix.zhtml?c=251847&p=irol-newsArticle_print&ID=2378298

Where is the data? It is not just Citron, it is friggin' Medicare and every insurance company who has noted that there is no real clinical data behind Acthar.

Where did the \$400 million go? Everyone knows....Paying off Doctors.

Without going into more detail, we all know, Mark Trudeau has lied to Wall Street for years and he still has his job because that is the only way to be the CEO of MNK.

OIG from Health and Human Services

This major blow to the Acthar bull thesis comes the same month that the Office of Inspector General (OIG) for the US Department of Health and Human Services (HHS) disclosed a ruling that Mallinckrodt could not give hospitals vials of Acthar for babies with infantile spasms.

<https://citronresearch.com/wp-content/uploads/2018/11/AdvOpn18-14.pdf>

The language from the HHS OIG is far more relevant now that we know that the drug does not work. The government actually specifically called out the “fraud” and “abuse risks” of the proposed scheme as they noted:

“Certain publicly available information that relates to the subject of this request for an advisory opinion illuminates our analysis of the fraud and abuse risks posed by the Proposed Arrangement.”

Does our government not want to cure sick babies or does our government know that Mallinckrodt is the face of greed in the pharmaceutical industry?

It’s All About Medicare

As exposed by Citron and detailed by numerous media outlets, Mallinckrodt is heavily dependent on Medicare reimbursement for Acthar.

Knowing this, CEO Mark Trudeau has previously lied about what percentage of Acthar revenue comes from Medicare.

<https://www.cnbc.com/2016/11/16/mallinckrodt-shares-tank-as-short-seller-andrew-left-claims-ceo-commits-fraud.html>

<https://edition.cnn.com/2018/06/29/health/acthar-mallinckrodt-medicare-claims-doctor-payments/index.html>

In a largely unnoticed memo put out a few months back, the Medicare Payment Advisory Commission (MedPAC) reported to Congress the abuses of Acthar:

“Between 2001 and 2017, the average price per vial increased from \$748 to \$38,000. Between 2011 and 2015, Medicare spending for Acthar increased from \$49 million to \$504 million. Fewer than 2,000 clinicians prescribed Acthar to beneficiaries in 2015, and 71 percent of them received at least one nonresearch payment from the manufacturer of Acthar related to the drug. These financial relationships raise questions about conflicts of interest among prescribers of Acthar.”

http://www.medpac.gov/docs/default-source/reports/jun18_ch10_medpacreport_sec.pdf?sfvrsn=0

Not only is MedPac reporting to Congress that doctors are being given kickbacks, but they also acknowledge that Acthar had “little or no clinical benefit”.

For bulls that tout the Company's case studies, MedPac noted that:

“Most of the studies of Acthar for adult conditions are small, retrospective or prospective observational studies that do not compare Acthar with other drugs or placebo.”

<https://www.actharnephrology.com/acthar-clinical-experience/acthar-case-studies>

The Analysts Who Cant Shoot Straight

This morning, two different analysts defended MNK dismissing MedPac and the OIG and obviously minimizing the results of the study by sayingjust wait until the new data.

Because we are kind and nice people, we will not mention them by names, but they know who they are.

Note that both of these analysts have had price targets of over \$100 on MNK and one as high as \$150.

So to steal a page from Bill Maher (New Rules)

“If you are an analyst and you cover a stock and it falls 95% from your price target you are never able to comment on the stock ever again.”

We could editorialize and comment for days, but it looks like the government is now starting to do our job for us.

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