

# Mystery Fungus Sparks NIH Crisis, Imperiling Trials, Patients, and Its Boss

(Subtitle: A Fungus Among Us)

Journal Article by Thomas M. Burton



## Crisis response at the NIH in Bethesda, MD has triggered delays in treatment and put its chief, Francis Collins in the hot seat.

- 19 months ago a fungus was found to be growing in two medicine vials in an NIH pharmacy.
- This discovery has caused delays for many patients seeking treatments for colon cancer, melanoma, gastrointestinal and chest tumors, among other diseases.
- NIH Director Collins has been criticized for his handling of the situation and could face replacement by the new Presidential administration.



# The fungus is discovered...

- May 19, 2015 Dr. Collins received a phone call from the FDA alerting him to an emergency inspection of the drug-making lab.
- An employee at the lab noticed a discoloration in a vial of medicine which turned out to be a fungal contamination in a total of two separate vials of medicine.
- The lab was closed and after 5 FDA inspections that month, it was determined the fungus was the result of faulty air flow in the lab, as well as several other issues that can disrupt a sterile pharmacy environment.
- Collins determined no subjects were harmed as a result of the contamination and the technical problems were the fault of the hospital pharmacy managers, who were suspended, then re-assigned to other NIH positions.



## The fungus is discovered...

- Two senators responsible for funding the NIH's 32-Billion dollar budget urged Collins to convene an independent investigative panel to look into the incident. They would be called "The Red Team."
- The Red Team was composed of medical and pharmacy experts who would spend 3 days interviewing senior NIH officials.
- The report was released in April 2015 and the panel found a severe lack of compliance in the NIH pharmacy.
- The panel reported an "evolution of a culture and practice in which patient safety gradually, and unintentionally, became subservient to research demands."

"My overall impression is that the Clinical Center doesn't meet the standards you need to have when dealing with human lives"

- Norman Augustine,  
former chair of  
Lockheed Martin and  
Red Team Panel  
member.

The fungus is discovered...

Dr. Collins reported the NIH pharmacy's troubles were not an isolated event, but a reflection of institutional failures about compliance and attention to patient safety.

"I felt I had no choice, but to take it with great seriousness, and not put a band aid on it"

– NIH Director Collins

## NIH Staff Reactions to Collins Actions

- NIH staff including doctors and nurses refuted Collins' claims and disagreed with his response to the event, citing his decisions as an unwarranted attack on the hospital's reputation.
- The staff have blamed Collins for low employee morale.
- The hospital specialty pharmacy remains closed as of the publication of this article.
- Because Collins' boss is the US Government, they can replace him if they like. With the new administration in the White House, this is entirely possible.

“The destruction of this fine-tuned medical machinery and its service to patients and scientists is a tragedy,”

-Marcus Heilig,  
former NIH Clinical  
Director and critic  
of Collins

# The NIH has been struggling as a result of this discovered contamination

- Patient enrollment at the NIH fell 37% last year between April and December as a result of a slow down in research and lack of willingness of doctors to refer patients to the NIH for treatment.
- NIH's immunotherapy lab at the cancer institute was closed for three months last year and now operates at a reduced speed.
- Many men and women who cannot find successful treatment elsewhere and have few options available have been turned away due to the closure.

“We’re turning away many people, the overwhelming majority of whom have metastatic cancer not responding to other treatment,”

-Steven A. Rosenberg, NCI Chief of Surgery

# The NIH has been struggling as a result of this discovered contamination

“This has not only set back our science and our protocols, it has delayed cancer patients’ treatment by a year and a half. For a cancer patient, treatment substantially delayed is treatment denied.”

-Jay Berzofsky, researcher

“We’re turning away many people, the overwhelming majority of whom have metastatic cancer not responding to other treatment,”

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## Let's discuss Dr. Collins' approach...

- Do you agree with how he handled this event; are the repercussions too harsh?
- Do you disagree with how he handled this event; are the repercussions not harsh enough?

# Examples of Events at Penn Pharmacy

1. The case where IDS used lactose instead of glucose to create the placebo when the protocol called for the other to be used
2. The case where IDS improperly packaged the product (not per protocol) for participants by not including the right amount of placebo versus active product (it was a double-blind study) and they completely destroyed the data integrity .

# Examples of events at Penn Pharmacy

3. The case where PCAM pharmacy accepted, stored and dispensed expired study medication.

4. The case where the sponsor reported that some of the vials of study medication was contaminated with glass fragments for a research study where infants were the targeted population. At least five subjects enrolled at Penn received the study medication during this time.

## Examples of events at Penn Pharmacy

5. PCAM Pharmacy received the drug and stored it in the refrigerator instead of room temperature, per protocol. It was found this did not harm any subjects, however a deviation was reported and reviewed by the Convened board.

## Conclusion...

Do you think that Penn would do what Dr. Collins did to protect patient safety?