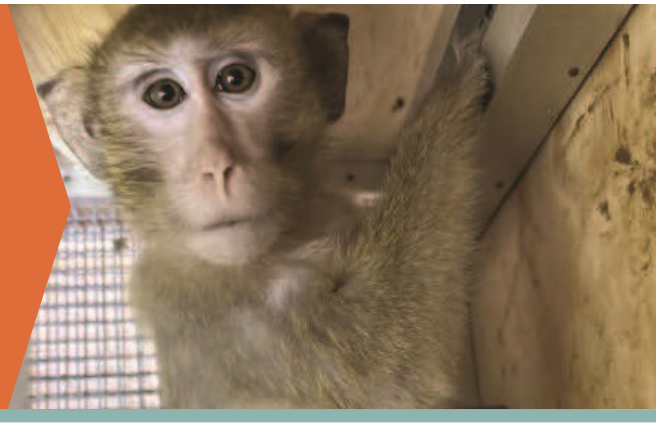
HEPATITIS A

Hepatitis A infections in macaques have compromised the evaluation of drug safety candidates, undermining the integrity of FDA-required testing.



Hepatitis A

Hepatitis A virus (HAV) is a highly contagious virus spread through the fecal-oral route. Although widely recognized as a human health threat, its presence in the primate research pipeline has been overlooked, putting both research outcomes and worker safety at risk. Primates used in laboratory studies are expected to be free of such infections—but recent cases show that this is not always the reality.

Compromised Research

- In a 2024 *International Journal of Toxicology* study, 20 of 42 long-tailed macaques from Mauritius turned out to be carrying HAV. Their elevated liver enzymes were initially mistaken for drug toxicity, stalling development and delaying FDA submissions. Only after the study was repeated in HAV-free macaques did researchers confirm that the compound was not toxic to the liver.[1]
- In 2022, a previously unrecognized HAV genotype was identified in Mauritian macaques at a German facility. The virus triggered liver abnormalities, lingered in the monkeys for months, and escaped detection until deep sequencing revealed it.[2]

These cases highlight a critical gap in current screening protocols: HAV-infected monkeys can appear healthy and test negative but still contaminate research.

Worker Safety at Risk

Monkeys can shed HAV virus without showing any signs of illness, making it difficult to detect and control. This silent transmission creates an ongoing risk for staff who handle animals, bedding, cages, or contaminated waste.

Unlike mild gastrointestinal viruses, HAV in humans can cause jaundice, liver inflammation, and vomiting and require weeks-long recovery. Undetected infections in research colonies put workers directly in harm's way and raise serious legal and reputational risks for facilities.

The Bottom Line

HAV is now a documented threat in the primate research pipeline. It has already compromised study data and exposed critical failures in sourcing and screening. These are not isolated incidents; they reveal systemic vulnerabilities that demand urgent attention.

Endnotes

[1] Powell CJ, Kapeghian JC, Bernal JC, Foster JR. Hepatitis A virus infection in cynomolgus monkeys confounds the safety evaluation of a drug candidate. *Int J Toxicol*. 2024;43(2):108-117. doi:10.1177/10915818241235122

[2] CDC Mecklenburg L, Ducore R, Boyle M, et al. A new genotype of hepatitis A virus causing transient liver enzyme elevations in Mauritius-origin laboratory-housed *Macaca fascicularis*. *Vet Pathol*. 2024;61(3):488–496. doi:10.1177/03009858231209691

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