



BARDA INDUSTRY DAY

Emergency Use Authorization for MCMs

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MCM Portfolio

- BARDA's portfolio includes medical countermeasures (MCMs) to respond to a variety of "CBRN" threats:



CHEMICAL



BIOLOGICAL



RADIOLOGICAL



NUCLEAR

- BARDA's portfolio expands to incorporate new MCMs in response to various emerging threats....





CBRN...Z?



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[emergency.cdc.gov](https://www.emergency.cdc.gov)



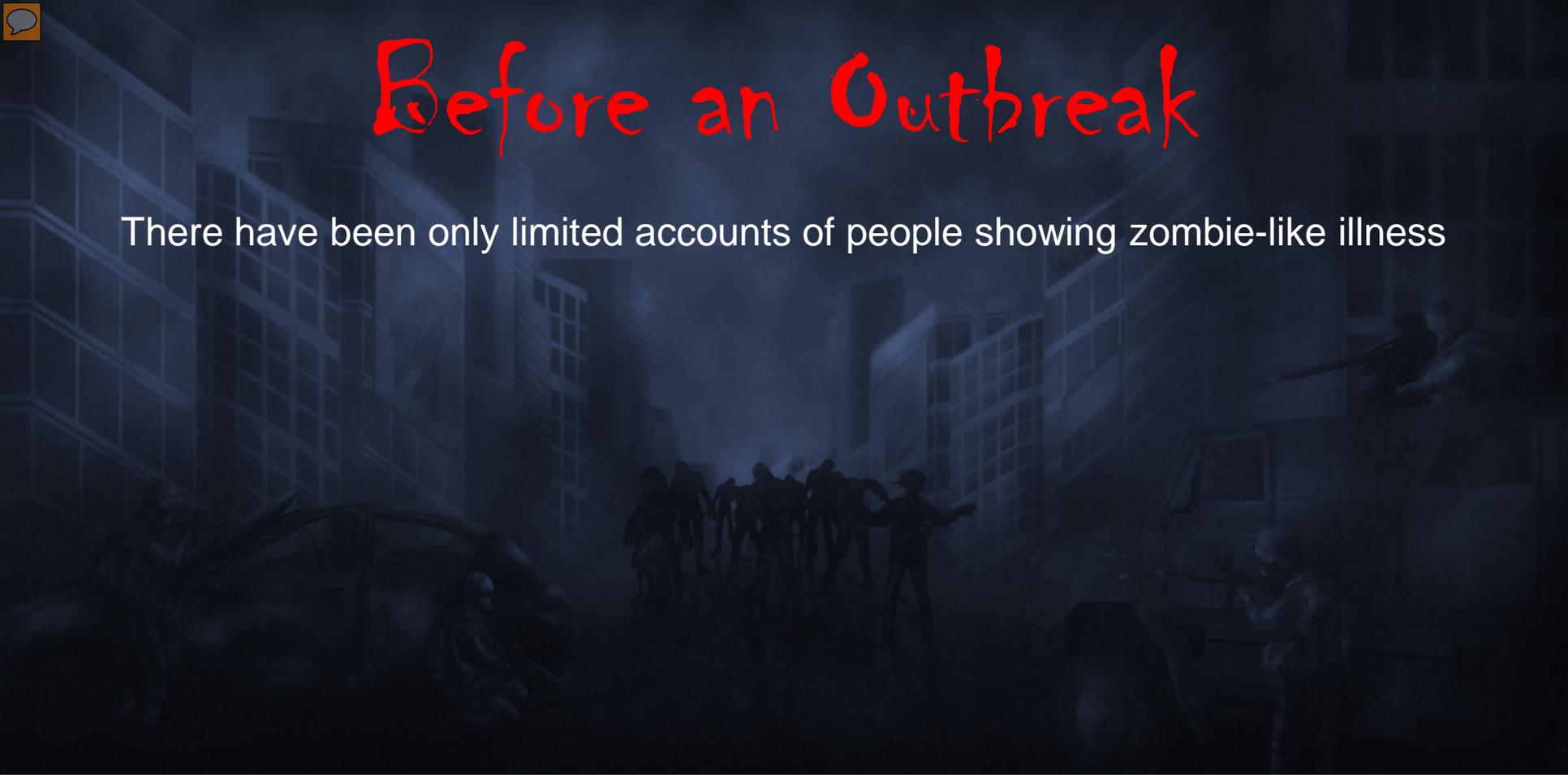
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Before an Outbreak

There have been only limited accounts of people showing zombie-like illness



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Pre-Emergency Use Authorization

- Engage with FDA in non-emergency scenarios to:
 - Allow time for review/feedback from FDA for a robust submission
 - Expeditious review during an emergency
- Part of the USG's preparedness plans for MCMs that BARDA seeks to procure for inclusion in the Strategic National Stockpile



What a Pre-EUA/EUA IS and IS NOT



A legal mechanism that allows use of an unapproved medical product or unapproved use of an approved medical product during a CBRN emergency or when there is a potential for a CBRN emergency



A regulatory milestone or stopping point

For additional FDA information about the EUA authority, see final guidance (2017):

<https://www.fda.gov/regulatoryinformation/guidances/ucm125127.htm>



Pre-EUA & EUA Process

- Predicated on the understanding of what is needed for FDA to authorize an EUA in an emergency:
 - Serious or life-threatening disease or condition
 - Evidence of effectiveness
 - Risk-benefit analysis
 - No alternatives





BARDA Prepares!

- RoMero Inc. has developed zombicillin as treatment for the zombie virus (ZomV)
- Regulatory status:
 - Phase II/III studies
 - BARDA is supporting RoMero Inc. for advanced development of zombicillin
 - BARDA engaged with RoMero Inc. to acquire zombicillin
- Zombicillin meets an unmet medical need:
 - There are no other approved, available, alternative MCMs to treat ZomV

Pre-EUA Activities

- BARDA requests the following documentation from RoMero Inc. at least **3 months*** prior to the submission:
 - Letter of Cross Reference Authorization
 - Investigator's Brochure
 - Information to support use of the product:
 - ✓ Final study reports or summaries of safety/efficacy data or preliminary data from nonclinical and clinical studies
 - ✓ Protocols/tabular summaries for nonclinical and clinical studies
 - ✓ Published studies and/or other publications

**** In a non-emergency scenario, more time is available to develop the Pre-EUA***



Content of Pre-EUA

- Unmet medical need
- Risk/benefit analysis
- Safety and effectiveness



Content of Pre-EUA

- Why take zombicillin for ZomV
- How to take zombicillin
- Risks/side effects
- Benefits
- Instructions for certain populations

**Fact
Sheets**



Who, What , Where, When...



GOAL

FDA provides a “*no further comments*” notification

**Note – for Pre-EUAs, these are not PDUFA submissions and there is no review clock for FDA*



Who, What , Where, When...

- Under the Pre-EUA, zombicillin is brought into SNS
- RoMero Inc., continues development of zombicillin
 - Provides updated product information
- Pre-EUA is revised with the most up-to-date information





Then... if the most feared day
becomes a reality.....



An Outbreak Happens



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BARDA Responds!



GOAL

FDA
authorizes
the EUA





Thank You



No more zombies have returned from the grave! A successful response!



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