

## Chapter Five: 2001 Anthrax Letters

Author's Note: The analysis and comments regarding the communication efforts described in this case study are solely those of the authors; this analysis does not represent the official position of the FDA. This case was selected because it is one of the few major federal efforts to distribute medical countermeasures in response to an acute biological incident. These events occurred more than a decade ago and represent the early stages of US biosecurity preparedness and response; however, this incident serves as an excellent illustration of the types of communication challenges expected in these scenarios. Due in part to the extended time since these events and the limited accessibility of individual communications and messages, this case study does not provide a comprehensive assessment of all communication efforts. In contrast to the previous case studies in this casebook, the FDA's role in the 2001 anthrax response was relatively small, and as such, this analysis focuses principally on the communication efforts of the CDC and state and local public health agencies. The 2001 anthrax attacks have been studied extensively, and the myriad of internal and external assessments led to numerous changes to response and communications policies and protocols. The authors intend to use this case study as a means of highlighting communication challenges strictly within the context of this incident, not to evaluate the success or merit of changes made as a result of these events.

### Abstract

The dissemination of Bacillus anthracis via the US Postal Service (USPS) in 2001 represented a new public health threat, the first intentional exposure to anthrax in the United States. The attacks resulted in 22 cases of anthrax—eleven inhalational and eleven cutaneous—five of which were fatal.<sup>1</sup> Public health officials faced the challenge of communicating risk during rapidly evolving circumstances in response to terrorist attacks that affected numerous states and Washington, DC. A total of 21 USPS facilities were contaminated in the attacks, and 32,000 potentially exposed persons initiated post-exposure prophylaxis.<sup>2</sup> These attacks followed closely after those of September 11th, further complicating the challenge of addressing a new threat in a nation still recovering from a traumatic event.<sup>3,4,5</sup> Conflicting public health guidance across different government jurisdictions and changing directives about prophylaxis undermined public confidence in health authorities' handling of the crisis and in the recommended personal protective actions, particularly among affected minority populations.

### Background

### Florida

On October 2, 2001 the index patient was taken to an emergency department in Palm Beach County, Florida. After an examination and further testing, clinicians suspected inhalational anthrax and contacted the Palm Beach County Health Department. On October 4, Florida State Department of Health and Centers for Disease Control and Prevention (CDC) laboratories confirmed the presence of *B. anthracis* in samples from the index patient. The index case was a photo editor for a media company, and coworkers reported that he had opened and scrutinized a suspicious letter containing a white powder on September 19.<sup>6</sup> Despite receiving antibiotic treatment, the index patient died three days after seeking care.<sup>7,8</sup> This was the first case of inhalational anthrax in the United States since 1978 and would later be determined to be the first known use of anthrax in the United States as an agent of biological terrorism.<sup>6</sup> A coworker of the index patient was admitted to the hospital on October 1 for what was initially misdiagnosed as pneumonia and later also determined to be inhalational anthrax. This second patient also received antibiotic treatment and ultimately survived.<sup>9</sup>

The epidemiological investigation identified *B. anthracis* in the mail and package area of the patients' workplace.<sup>8.10</sup> Environmental samples from local and regional postal centers that processed mail sent to the office also tested positive for *B. anthracis*.<sup>10</sup> Nearly 1,100 people in Florida began post-exposure prophylaxis (PEP) for suspected anthrax exposure.<sup>11</sup>

### New York City

On October 9, the New York City Department of Health and Mental Hygiene notified the CDC of a suspected case of cutaneous anthrax, prompting a second, parallel epidemiological investigation. The first identified New York anthrax patient had opened a letter containing a suspicious powder at her workplace, and she sought medical care for a skin lesion on October 1.<sup>8</sup> In total, seven people in New York acquired cutaneous anthrax and one individual acquired and died from inhalational anthrax. With the exception of an infant who visited his mother's workplace, all of the cutaneous cases handled mail at work. All of the patients with cutaneous anthrax in New York were treated with ciprofloxacin—at the time only available as name-brand Cipro—and all survived.<sup>1,2,8,10,12</sup> In total, more than 2,200 exposed persons were prescribed a full sixty-day course of antibiotic PEP in connection with the New York incidents.<sup>11</sup>

### New Jersey

On October 1, a USPS mail carrier in West Trenton, New Jersey sought treatment at a local hospital for a skin lesion on her arm.<sup>i</sup> Ultimately, six individuals in New Jersey—five of whom worked in postal facilities—developed anthrax. Two of the individuals developed inhalational anthrax, while the remaining four cases were cutaneous anthrax.<sup>2,12</sup> Environmental testing confirmed the presence of *B. anthracis* spores at the Trenton Processing and Distribution Center — where four of the cases worked and contaminated

<sup>&</sup>lt;sup>1</sup>Some regulations also apply if the product is manufactured in the United States, even if not being developed under a US IND.

letters transited en route to New York and Washington, DC.<sup>13</sup> While most of the earlier cases in other jurisdictions were exposed through handling contaminated letters, the anthrax cases at the postal distribution facility suggested that automated, high-speed sorting machines could cause the release of anthrax spores into the environment. More than 1,400 persons in New Jersey received sixty-day courses of PEP as a result of suspected anthrax exposure.<sup>11</sup>

### Washington, DC

On October 15, a staff member for Senate Majority Leader Tom Daschle opened a letter in the Hart Senate Office Building, releasing a white powder. Preliminary tests indicated the presence of *B. anthracis* spores, and the immediate area was evacuated. Based on environmental sampling, nasal swabs, and tracing of the envelope's delivery, investigators determined that 625 persons who worked at the Hart Senate Office Building, a nearby mail sorting facility, and mail rooms in two other Congressional office buildings were at risk of exposure. These at-risk persons were provided with a full sixty-day course of antibiotics.<sup>14</sup> On October 19, an employee of the Brentwood USPS distribution facility in Washington, DC was admitted to a Virginia hospital and diagnosed with inhalational anthrax. Ultimately, five DC-area individuals were infected with inhalational anthrax, two of whom died. Four of the patients worked at the Brentwood facility, which had processed the letter mailed to Senator Daschle's office.<sup>15</sup>

The USPS closed the Brentwood facility on October 21, 2001, and it remained closed until December 2003.<sup>10,16</sup> Officials initially recommended PEP only for employees working near the worksite of the first case, but this quickly expanded to include all postal workers in DC-area facilities served by the Brentwood distribution center.<sup>10</sup> The Washington, DC; Virginia; and Maryland health departments provided full sixty -day courses of PEP directly to nearly 1,900 of 2,400 Brentwood employees, and more than 800 additional persons throughout the Washington, DC area were provided prophylaxis in connection with the Daschle letter.<sup>11,15</sup>

### **Connecticut**

On November 16, a Connecticut woman was hospitalized with inhalational anthrax and died four days later. The victim was homebound and lived alone in a rural area of Connecticut. Although the source of this victim's exposure to *B. anthracis* was never identified, genetic testing linked her case to the bioterror attacks. Despite no positive environmental samples or nasal swabs, officials offered PEP to the victim's family and friends as well as postal workers from two Connecticut facilities.<sup>17</sup> More than 1,200 persons in Connecticut were ultimately prescribed full sixty-day courses of antibiotics.<sup>11</sup>

### **Communication Milieu**

In 2001, most Americans were unfamiliar with anthrax or its symptoms and treatment regimens. As a result, they relied heavily on public health officials for information and guidance. With little practical experience with anthrax experience, federal, state, and local officials were forced to develop key information and response recommendations in real time.<sup>5</sup> Additionally, the speed with which events unfolded required officials to address questions and implement response procedures with an incomplete and evolving grasp of the situation. Due to the considerable uncertainty surrounding the attacks, official guidance changed dramatically as the incident progressed. Finally, due to the sheer number of jurisdictions involved, there were many instances of state and local policies conflicting with federal recommendations as well as various organizations presenting contradictory information. These missteps instilled a sense of mistrust among Americans, particularly those directly affected by the attacks.

# DILEMMA #1

An evolving health crisis with a high degree of uncertainty generated acute demands for timely information, which leaders were not prepared to meet.

The CDC and other clinical and public health experts struggled to effectively communicate risk to the public and healthcare professionals in the absence of complete information about the situation. This challenge was exacerbated by their limited experience dealing with anthrax, particularly on such a large scale and in the context of bioterrorism.<sup>5,18,19,20</sup> As new information became available, public messaging evolved, at times significantly changing or contradicting previous communications.<sup>21,22</sup> Risk assessments, environmental and clinical sampling techniques, and PEP recommendations all underwent substantial changes over the course of the response. When federal agencies were unable to effectively justify these changes, they were met with resistance. Additionally, health officials at the federal, state, and local level found it difficult to dedicate resources to addressing the media, making it difficult to control the public message. The absence of established procedures to respond to inquiries forced the public and media to seek out other, often unofficial, sources of information, resulting in contradictory messaging and further confusion.<sup>5,19,23</sup>

At the time of the 2001 anthrax attacks, little anthrax expertise existed in federal, state, or local health agencies, resulting in inconsistencies in messaging as information was gathered. The CDC's experience with anthrax at that point largely dealt with naturally occurring outbreaks rather than intentional releases, which combined with the sheer scale of the response, forced many health officials to operate outside their area of expertise. The public and media perceived this lack of expertise as an attempt to conceal information about ongoing response efforts and the threat posed by the disease.<sup>18,24</sup> For example, the CDC initially believed that sealed envelopes did not release anthrax spores and assured Brentwood postal employees that they faced minimal risk of contracting the disease. Once their fellow employees fell ill, however, the workers questioned the effectiveness of the CDC's response.<sup>18,23,25</sup>

Federal officials also faced communication challenges surrounding PEP recommendations. In 2000, the FDA approved labeling for the drug ciprofloxacin—at the time of the anthrax attacks, only available as name--brand Cipro—that included PEP for inhalational anthrax as an indication, and this remained the

only product specifically labeled as such until October 2001. In the midst of the anthrax response, the FDA clarified that the approved indications for doxycycline and penicillin—both available in a number of generic forms—included prophylaxis for inhalational anthrax exposure, and provided corresponding dosing information. They encouraged manufacturers of these products to submit applications for corresponding label supplements. While both drugs were already FDA-approved for both PEP and treatment for anthrax—the new label merely clarified the indications<sup>26</sup>—the label change was widely reported as new approvals for doxycycline and penicillin as PEP for inhalational anthrax.<sup>21,27,28</sup> Subsequent to the FDA announcement—and upon determination that the strain of anthrax used in the attacks was susceptible to doxycycline—the CDC updated its PEP drug of choice from ciprofloxacin to doxycycline. Doxycycline was equally effective as PEP, cheaper, resulted in fewer side effects, and was more widely available than Cipro.<sup>21,29,30</sup> Additionally, there were concerns that widespread use of ciprofloxacin could result in anthrax (and potentially other bacteria) developing resistance to a powerful antibiotic.<sup>21</sup> Because the initial anthrax patients and exposure populations were provided Cipro, the name-brand product was already widely publicized in the media as the best option to combat anthrax.<sup>31,32,33</sup> Regardless of the fact that CDC recommended the drug itself, ciprofloxacin, and not specifically the name-brand product,<sup>8</sup> Cipro was the only version of ciprofloxacin available at the time, making it difficult to distinguish between guidance and endorsement. Without strong, consistent communication from officials at the FDA, CDC, and other federal agencies with respect to the new labeling and updated MCM guidance, particularly in the face of significant media publicity for Cipro, many were confused by the shift to doxycycline, including public health and healthcare professionals.<sup>5</sup>

At the completion of the initially prescribed sixty-day course of antibiotics, the CDC offered another forty days of antibiotics and vaccination to individuals with high exposure levels and those who had not completed the initial course of antibiotics in order to reduce the risk due to *B. anthracis* spores still remaining in the lungs after sixty days.<sup>34</sup> This change led to concerns over the efficacy of Cipro and doxycycline and revisited questions regarding anthrax vaccine safety. Prior reports of negative side effects during the military's vaccination program led many to question the vaccine's use in civilians.<sup>35</sup> Furthermore, while military service members were given six doses of the vaccine over an 18-month period,<sup>36</sup> the civilian victims of the anthrax attacks were only offered three doses over four weeks.<sup>37</sup> The vaccine was not FDA-approved for PEP, so the government required a signed informed consent form—which many believed waived their rights to compensation for adverse side effects—as well as consent to follow-up observation under Investigational New Drug (IND) policies.<sup>37,38</sup> The vast majority of those offered the vaccine refused it, some believing that the government was simply taking advantage of the attacks as an opportunity to test the vaccine in human subjects. Of those who were offered the vaccine that

had already completed a sixty-day course of antibiotics, many perceived their continuing risk as low and were reluctant to take additional drugs with potential adverse side effects.<sup>35</sup> The failure of health authorities to effectively communicate justification for these policy changes and the informed consent and follow-up requirements under the IND protocol led many to doubt the competence and authenticity of the local and federal officials leading the response efforts.

At times, communication problems began with a misinterpretation of information, and without effective communication mechanisms in place to respond, small mistakes quickly became national issues. In one example, a state health representative was called to an emergency meeting with the Governor, leaving a local health official to lead a meeting with New Jersey postal workers. In addressing the postal workers, the local official misspoke about two local "suspect" anthrax cases—both individuals, in fact, had positive nasal swabs but no positive diagnostic test or symptoms. The situation grew worse when state health officials were unavailable to confirm or clarify the statement for the media. Subsequently, a local paper ran the story on the suspect cases, which was then picked up nationally by CNN. This incident underscores the challenges of sharing accurate information in an uncertain environment and the absence of well-informed response authorities and communication protocols.<sup>20,39</sup>

Healthcare providers also struggled to obtain timely, consistent guidance from health officials.<sup>4</sup> When federal officials did have pertinent information to share with the medical community, they did so through inadequate mechanisms. For example, CDC officials published updates in their Morbidity and Mortality Weekly Report (MMWR). Though these reports are freely available, their weekly periodicity was insufficient for keeping pace with a rapidly evolving incident. The CDC also utilized two fledgling technologies, Epi-X and the Health Alert Network (HAN), to share updates; however, access to these in 2001 was limited, particularly for healthcare providers. The CDC did publish updates to its public website, but the site crashed multiple times during the response, due in part to high traffic.<sup>5,23</sup> The CDC's inability to provide timely, accurate, and easily accessible information resulted in inconsistent messaging and created an information void that unofficial, less reliable sources were left to fill.<sup>4,23</sup>

### Implications for the Future

All disasters, including acts of bioterrorism, are inherently replete with uncertainty; however, training agency representatives in the following steps can help ensure effective emergency communication with the public: acknowledge the uncertainty; explain efforts to gather and analyze information; explicitly respond to requests for information, even if only to state openly that the answer is currently not known; and offer situational updates as the crisis progresses.<sup>18,22,24,35,39,40</sup> These efforts will promote transparency and garner

a sense of trust in the response. Advance preparation to deal with a rapidly evolving and ambiguous situation includes establishing streamlined protocols for message dissemination in order to reduce delays in communication.<sup>40</sup> Federal agencies also need to ensure that clinicians receive accurate updates. Increased access to technology—including HAN and Epi-X—provides means to rapidly disseminate technical information; equipping clinicians with key messages will better enable them to engage their patients.<sup>23,42</sup> Efforts are required, however, to ensure that key audiences have access to these new technologies in advance of an event. Even under ideal circumstances, the public will predictably seek out alternate information sources, so it is vital for official representatives to protect their credibility as authoritative sources of information by communicating early, openly, and often. Still, mistakes will inevitably be made during any emergency. Acknowledging errors, directly addressing policy changes, and updating public messaging accordingly will help maintain agency transparency and credibility throughout the response.<sup>18,39</sup>

# ACTION ITEMS FOR FDA

- 1) Employ crisis communication strategies and language that can help the agency toFDA preserve its credibility and remain responsive to information demands by the public, media, and healthcare providers during periods of uncertainty:
  - a) Acknowledge limits on the ability to determine or predict all aspects of the emergency and response due to missing, complex, or rapidly evolving information.<sup>44</sup> Do this apologetically and self-critically, and share in the audience's distress at having incomplete knowledge—eg, "It must be difficult for people to hear how tentative we must be, because there is still so much we don't know..."<sup>45</sup>
  - b) Describe the process being used to obtain additional information about the evolving situation—eg, "I can't tell you today whether investigational drug 'X' is effective in humans against the current outbreak of disease, because we only have results from laboratory and animal studies. But I can tell you what we're doing to find out..."<sup>46</sup>
  - c) When policy positions shift in a crisis, alert the audience, explain how and why the message is different from before, and acknowledge the emotive response(s) that the change may evoke—eg, "More evidence has come to light during the outbreak, indicating that investigational drug 'X' is not safe and has no benefits in humans. We have, therefore, halted its use in patients. We share your grief at this disappointing development."<sup>47</sup>
- 2) Coordinate with federal partners to increase the reach of vital messaging:
  - a) In this case, the CDC utilized technologies such as HAN and Epi-X to help ensure that the medical community was updated regarding recent developments in the anthrax response, including PEP recommendations. Coordinating with the CDC and other partners to leverage existing communication networks could provide additional means of informing clinicians, the public, and other audiences of the status of investigational products, product recalls, fraudulent products, and other vital information.
    - New communications technologies require planning, implementation, and testing—prior to an event—to ensure that desired audiences are being reached. In this case, HAN and Epi-X were utilized by the CDC, but they were not yet widely accessed by the intended audience, reducing their effectiveness.

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- b) Similar approaches should be utilized to expand the reach of social media communications. Coordinating with public information staff in other agencies can enable widespread sharing (eg, "retweeting" a message on Twitter) through and between expanded social networks to reach a broader audience.
- 3) Streamline social media communication approval processes to enable the FDA to respond rapidly to the public, media, and government officials. Monitoring and publicly replying to inquiries and comments on various social media platforms provides insight into how the public is receiving existing communications, helps identify topics that require additional effort or updated communication approaches, and facilitates responsive engagement with influential members of the media and public.

# DILEMMA #2

Contradictory messages and inadequate coordination of risk communication across multiple governmental jurisdictions and the private sector impeded response efforts and generated public mistrust.

Public health authority and responsibility resides largely at the state level, so response policies can vary significantly across states.<sup>5</sup> In addition to the three states (Florida, New York, and New Jersey) and Washington, DC where the initial cases were exposed, several other states were also involved in response activities. As previously mentioned, one of the infected postal workers from the New Jersey USPS facilities lived in Pennsylvania. Additionally, the letters sent to Washington, DC affected a number of people who lived in Maryland and Virginia but worked in the District. Initial recommendations in these three jurisdictions varied, and there was considerable confusion in the public over which to follow, those from where they worked or those from where they lived. For instance, prophylaxis recommendations in Maryland and Virginia followed CDC guidelines while Washington, DC had its own policy. Some jurisdictions made prophylaxis recommendations before the CDC issued guidance, and others waited for the CDC policy. In some cases the guidance issued by jurisdictions directly conflicted with CDC-issued recommendations. Furthermore, state and federal agencies used different criteria for identifying at-risk populations. Some definitions of "at-risk" were limited to those who handled contaminated envelopes, while other definitions encompassed service staff and visitors at affected facilities.<sup>5,48</sup>

Two significant policy contradictions regarding nasal swabs and the anthrax vaccine highlight the complexities associated with coordinating responses across multiple agencies and jurisdictions. First, nasal swabs can help identify the scope of exposure in and around areas known or suspected to be contaminated with *B. anthracis*; however, they are inadequate for use as a diagnostic or in determining individual-level exposure. Health officials immediately conducted nasal swabs to determine potential exposures for the Florida, New York, and Capitol Hill incidents.<sup>20</sup> Because the postal distribution centers in New Jersey and Washington, DC were not initially identified as contaminated, ten days passed between when the letters passed through the facilities and when health officials conducted nasal swabs at these locations.<sup>1,13,15</sup> Official federal and state guidance indicated that nasal swabs were not to be used as diagnostic tools for anthrax, but some hospitals and other facilities offered them at the demand of the local population and reported the results to local health departments. Nasal swabs routinely result in false positives and false

Negatives, which officials worried could give those tested an unwarranted sense of risk or safety, based solely on the swab results.<sup>20,22,43,49</sup> To reduce this risk, many of those persons swabbed by official responders were not provided the results of their test. Because the explanation for this was insufficient, it increased feelings that they were the subject of experimentation.<sup>22,43</sup> The general misunderstanding, in the public and medical community, of the purpose and reliability of the nasal swab tests and the local deviation from state and federal guidance led to further public mistrust of health officials. Additionally, the CDC's delay in conducting nasal swabs at the Brentwood facility was viewed by many, especially the Brentwood employees, as substandard care for poor, minority populations compared to the exposed population on Capitol Hill.<sup>24,43</sup>

In December 2001, CDC and other Department of Health and Human Services officials announced that they would offer the anthrax vaccine to certain subsets of the exposed population, a decision met with opposition from the public as well as state and local governments. The initial justification for the change indicated that those with high levels of exposure to anthrax spores and those who did not complete their initial sixty-day course of antibiotics could still be at risk for developing anthrax after sixty days.34,37 Despite offering the vaccine, federal health officials remained uncertain about how the vaccine's potential benefits weighed against possible side effects. Consequently, they neglected to take a definitive stance on whether exposed populations should be vaccinated. This perceived lack of conviction, combined with the investigational nature of the vaccine and the perception that the government



offering the vaccine was motivated by political rather than medical factors, left many questioning whether vaccination was the right decision.<sup>25,35</sup> Compounding the public mistrust, the vaccination plan received considerable pushback from the postal worker union and the health departments in New Jersey and Washington, DC.<sup>35,50</sup> Finally, while federal health officials discussed the vaccination directly with affected

Senate staffers, they coordinated with state officials, the USPS, and the postal worker union to disseminate information to the rest of the exposed population. The vetting process in each of these organizations resulted in delays in the information reaching the affected populations and intensified fears that these organizations, particularly the USPS, were weighing the benefits to their constituents against their own interests. The effect of inconsistent messaging is evident in the vaccination rate for the Senate staff (38%) compared to the affected media and postal workers (2%).<sup>50</sup>

The public's mistrust in federal, state, and local leadership was attributable, in part, to unfamiliarity with the agencies responsible for responding to health emergencies. Without having any prior relationship or interactions with the CDC, for example, many found it difficult to trust the messages that the CDC disseminated, particularly when those messages changed or conflicted with information coming from other agencies. As a result, most of the affected population sought out local health officials, friends and family, the internet, and/or the media as information sources.<sup>18,42</sup> Some also assumed that the federal agencies and state and local public health agencies worked closely together and collaborated to rapidly share information, which was not always the case.<sup>18</sup> In fact, reports indicate that state and local governments vetted risk communications from senior governmental sources before presenting them to the public, often resulting in delays and changes to the message content.<sup>39</sup>

### Implications for the Future

One key to effective risk communication during a disaster is coordination between relevant agencies and stakeholders prior to the incident.<sup>4,19,51</sup> Pre-established relationships enable responders and organization representatives to learn about other entities' respective priorities and capabilities, thereby facilitating greater coordination during an emergency. Utilizing multidisciplinary task forces for daily operations and preparedness planning breeds familiarity between agencies and promotes collaboration across jurisdictional and agency lines.<sup>25,52,53</sup> When stakeholders cooperate and maintain the same operational picture, communication can be decentralized, decreasing delays and promoting proactive—as opposed to reactive—communication.<sup>19,20,39</sup> Risk communication recommendations often include the principle of "speaking with one voice." Even so, stakeholders may evaluate circumstances differently and reach conflicting conclusions. Directly addressing the basis and rationale for these differences will engage the public, allow them to make informed decisions, and promote trust within the community.<sup>35,39</sup> Additionally, engaging journalists in preparedness efforts helps ensure that media understands the rationale for these changes or differences in MCM and emergency response policies and accounts for them in their coverage of health emergencies.<sup>40</sup> Finally, pre-event coordination between responders, the media, and other stakeholders — such as informational workshops and exercises — should include risk communication

development and dissemination protocols to facilitate rapid, accurate transmission of vital messaging during an incident to a variety of audiences.<sup>5</sup>

Even with ideal pre-event planning and coordination, certain aspects of incident responses may remain foreign to the public. Illustrated here by the public's unfamiliarity with the CDC, this issue can also pertain to lesser known programs or policies within well-known agencies as well as novel diseases or prophylaxis or treatment options. Even with increased public access to governmental agencies and representatives today—via increased traditional and social media presence and agency websites—some aspects of incident response may remain largely unknown to the public. This places the burden on agencies to raise their individual and collective response profiles prior to an emergency and be proactive and responsive to demands for information on unfamiliar aspects and issues in ways that garner broad understanding in order to counter competing messages before they can take root.

# ACTION ITEMS FOR FDA

- Continue to strengthen PHEMCE interagency coordination and collaboration, including concerted efforts to "ensure effective communications with both responders and the public through the timely release of credible, understandable, and actionable information both prior to and during public health emergencies."<sup>54</sup> Maintain the FDA's frequent contact with state/local public health authorities and responders and public health non-governmental organizations to support their MCM preparedness and response capabilities,<sup>55</sup> and engender coordinated communications.
- 2) Enlist PHEMCE partners in a joint communication effort to develop, test, and promulgate an accessible narrative, supported by graphics, about the Strategic National Stockpile that projects a unified governmental effort to facilitate prompt, appropriate access to safe and effective MCMs in an emergency (from development to distribution to monitoring). Use this storyline in diverse public communications and single out FDA contributions, disseminating broadly, including at www.phe.gov.
- 3) Reinforce the FDA's public reputation as an agile emergency responder and credible information source on MCM safety and efficacy. Actively deliver information using, in particular, channels already integral to people's daily lives (eg, existing and emerging social media platforms, daily news or talk show programs on television or radio). Develop a network of respected and popular social media personalities to help deliver messages to people not currently monitoring FDA social media efforts.

# DILEMMA #3

Inconsistent public health interventions coupled with historic health disparities nurtured perceptions that health authorities delivered substandard care to, and even experimented on, certain populations.

Members of some affected populations believed that variations in public health recommendations reflected existing racial and socioeconomic disparities. In Washington, DC, for example, this perception was highly prevalent among the postal service employees at the Brentwood facility. USPS workers felt that the CDC should have recognized earlier that they were a high-risk population and provided care prior to the first identified Brentwood anthrax patient. Additionally, they were concerned not only that the treatment they received was inferior to that of the affected Senate staff, but also that the CDC and other health officials were more concerned with gathering data from them than addressing their individual concerns and fears.<sup>18</sup>

The CDC initially, and incorrectly, assumed that sealed envelopes did not allow for the aerosolization of anthrax spores and that exposure to anthrax required direct exposure to the open envelopes, and early indications otherwise did not prompt environmental sampling at postal distribution facilities.<sup>5,24,56,57</sup> In fact, testing and PEP did not begin at the Brentwood facility until October 21, two days after the first case was admitted to the hospital.<sup>15,24</sup> Workers at the Brentwood facility knew from the beginning that the sorting machines routinely damaged envelopes and that cleaning the machines required blowing significant quantities of dust into the air, potentially exposing workers far beyond the immediate area, but the CDC did not immediately reach the same conclusion. To many, the CDC's failure to identify the Brentwood employees as a high-risk group represented a significant disparity in the level of attention and care devoted to the Senate staff versus the Brentwood staff, many of whom belonged to racial minorities or came from lower socioeconomic backgrounds.<sup>5,18,43</sup>

In addition to the delay in initiating the investigation at the Brentwood facility, there were also differences between the prophylaxis options offered to the Senate and Brentwood staffs. When the Daschle letter was identified, the Senate staff were prescribed name-brand Cipro, in accordance with the initial CDC guidance.<sup>ii</sup> As discussed previously, clarified indications and updated labeling for doxycycline during the

<sup>&</sup>lt;sup>ii</sup> CDC guidance recommended ciprofloxacin, not specifically Cipro; however, name-brand Cipro was the only ciprofloxacin product available in the United States at the time.

Response led to revised CDC guidance, changing the preferred PEP from ciprofloxacin to doxycycline.<sup>21</sup> While doxycycline offered several significant benefits over ciprofloxacin,<sup>21,29,30</sup> the name-brand Cipro product was already widely portrayed in the media as the drug of choice.<sup>31,32,33</sup> When the postal workers at the Brentwood facility were provided with doxycycline as PEP, the fact that they received a generic drug resulted in the perception thtat they, being minorities and of low socioeconomic status, were being offered a substandard option compared to the name-brand product provided to wealthier, white Senate staffers.<sup>5,31,32</sup> Given the timing of the PEP policy change, postal workers viewed the difference between the response on Capitol Hill and at the Brentwood facility as disparities in care due to differences in socioeconomic status rather than as a necessary policy update based on new information.<sup>5</sup>

Brentwood employees also felt that federal health officials ignored the health and concerns of individual workers, reporting that CDC investigators merely gathered data instead of answering questions or mitigating public anxiety. For example, CDC teams arrived at the Brentwood facility to collect environmental samples while wearing biohazard suits, despite the fact that there were employees still working at the site.<sup>18,43</sup> Additionally, health officials were seen as working closely with the USPS leadership, who were viewed by the workers as prioritizing mail delivery and profits over employee health and safety.<sup>18,35</sup> Many of these concerns stemmed from historical examples of ethics violations such as the Tuskegee syphilis study, leading some postal workers to believe that the CDC was using the anthrax attacks as an opportunity to conduct human testing instead of helping them.<sup>18,24,35</sup> Reports from the Senate staff and the Brentwood employees also indicate significant differences in the level of attention they received from health professionals. The Senate staff had direct contact with the Office of the Attending Physician as well as consistent access to a single Navy physician. In contrast, postal workers reported that they met with many different federal health representatives who were rarely, if ever, available to address their questions and concerns.<sup>24</sup> By failing to effectively empathize with the Brentwood workers and address their individual fears, federal health officials alienated the postal workers and propagated feelings of socioeconomic and racial discrimination.

### Implications for the Future

In this case, feelings of discrimination were tied to delays in the CDC identifying the risk to postal workers and a failure to communicate justification for changes in PEP policy. During the initial phases of response, the CDC failed to identify postal workers as a primary risk communication audience. Had the CDC identified these workers as priority populations, their attention would have fostered a stronger sense of trust. Furthermore, by engaging these populations early on, the CDC may have better understood the risks faced by postal workers and potentially initiated PEP prior to identifying the first anthrax cases were Identified in postal workers.<sup>18,39</sup> Additionally, health officials need to be able to address the individual concerns of affected populations. While public health traditionally, focuses on population-level health, individual fears and questions are most important to those directly impacted by an incident. Such concerns must be acknowledged with empathy to foster trust, among affected individuals, assure them that their health and safety is a priority, and encourage compliance with official guidance.<sup>4,18</sup>

Empathizing with minority and other marginalized groups inherently involves understanding historical conflicts between these groups and the healthcare community. It is essential that health professionals are able to recognize public anxiety around the possibility of human experimentation and address concerns about clinical trials and epidemiological studies in the context of historical incidents.<sup>18,35</sup> To facilitate this, directed research to identify specific concerns within intended target audiences would provide context for framing complex ideas in emergency communications. Finally, leaders must ensure two-way communication throughout the response period, perhaps by assigning dedicated communications personnel or identifying and enlisting established advocates within affected populations.<sup>3,4,18,52</sup> Such advocates must able to elucidate complex issues for the population in question—such as informed consent, the difference between treatment and prophylaxis, or the purpose of collecting follow-up data—and provide responses to specific concerns.<sup>4,24</sup> By ensuring that all affected populations are properly informed of updated recommendations, risk communicators can empower the public to make informed decisions about their health and decrease feelings of discrimination and disparity.

# **ACTION ITEMS FOR FDA**

- Strengthen the Office of Minority Health's role in the Medical Countermeasures Initiative (MCMi) to better acknowledge, understand, and address special communications challenges involved with audiences that have historical mistrust in health officials. This added insight can help frame MCM communications, namely those involving clinical trials and investigational products, to reassure affected populations that equal treatment and consideration is given to all, regardless of race, religion, socioeconomic status, education, or other factors.
- 2) In conjunction with PHEMCE partners, and their respective experts in health equity and disparity, develop, test, and disseminate MCM messages that are culturally appropriate,, respond to community concerns,, and help foster a greater sense of trust within historically underserved and vulnerable communities. These messages can support enhanced accessibility to life-preserving MCMs in emergencies.

### Conclusion

During the 2001 anthrax attacks, public health officials faced significant challenges in communicating risk during a rapidly evolving public health crisis that spanned numerous states. Conflicting messages across jurisdictions and changing or inconsistent recommendations about treatment and prophylaxis undermined public confidence in health officials and led many to perceive significant disparities in care based on race and socioeconomic status. Public health officials can improve future emergency communication efforts by incorporating communication into preparedness planning and acknowledging uncertainty during incident response. Officials need to inform the public from the outset that guidance will evolve, acknowledge errors when they occur, and provide continuous updates throughout the course of an emergency to maintain transparency and enable the public to make informed decisions. Finally, health officials need to engage with the affected population to understand, acknowledge, and empathize with their individual concerns. Reassuring the affected population that health officials have their best interest in mind will build trust and encourage adherence to recommended actions.

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