April 25, 2025 Position Paper - Market Assessment: Prophylactic Opioid Countermeasures in the United States Strategic National Stockpile for Military Personnel and Chemical Incident Responders

I. Executive Summary

This report analyzes the market size within the United States Strategic National Stockpile (SNS) for medical countermeasures intended for the temporary prophylaxis of respiratory and/or nervous system depression in military personnel and chemical incident responders entering areas contaminated with high-potency opioids. The increasing threat of synthetic opioids, including their potential use as chemical weapons, necessitates specialized protective measures for these frontline personnel.[1] This analysis examines the mission and scope of the SNS, identifies relevant medical countermeasures[4], investigates government procurement activities[13], assesses potential threat scenarios and affected personnel[4], and estimates the market size based on available data. The findings indicate that the Department of Defense (DoD) is a primary driver of this niche market through its dedicated procurement of a 10 mg naloxone auto-injector specifically indicated for this purpose.[4] The role of the SNS, managed by the Department of Health and Human Services (HHS), in stockpiling this specific product for civilian responders is less evident in the available information, suggesting a potential area for future market development.

II. Introduction: The Strategic National Stockpile and the Emerging Threat of High-Potency Opioids

The United States Strategic National Stockpile (SNS) was established in 1999, initially known as the National Pharmaceutical Stockpile, to serve as a national repository of critical medical supplies for public health emergencies, with an initial focus on countering bioterrorism threats. Its primary mission is to supplement state and local medical resources during public health crises when local supplies are depleted or insufficient. Over time, the scope of the SNS has broadened to encompass a wide array of medical countermeasures (MCMs) designed to address diverse threats, including chemical agents and emerging infectious diseases. The management of the SNS falls under the purview of the Secretary of HHS, with guidance from the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), an interagency working group. Operationally, the SNS functions through a network of strategically positioned, secure warehouses across the United States, ensuring rapid deployment of needed supplies. Key components of the SNS include pre-configured 12-hour push packages for immediate, broad-spectrum response[18], a managed inventory system for tailored support based on specific incident requirements[28], and the CHEMPACK program for the forward placement of chemical agent antidotes. The evolution of the SNS from a focus on bioterrorism to a more comprehensive, all-hazards approach demonstrates its capacity to adapt to new and evolving threats, suggesting a potential for incorporating countermeasures against weaponized opioids. This adaptability is

evident in the SNS's responses to events like the September 11th attacks and the anthrax incidents in 2001, which led to a widening of its scope.[29] The ongoing emphasis on preparedness for emerging infectious diseases further highlights this flexible nature.

Concurrently, the United States faces a growing threat from high-potency synthetic opioids, such as fentanyl and its numerous analogues. These substances possess a significantly higher potency compared to traditional opioids, increasing the risk of accidental exposure and overdose. Of particular concern is the potential for these highly potent opioids to be weaponized and used in terrorist attacks or military conflicts. The increased potency of these agents often necessitates higher or multiple doses of naloxone, the standard opioid overdose reversal medication, to counteract their effects. A stark example of this threat was the 2002 incident in Moscow, where Russian special forces reportedly used aerosolized synthetic opioids during a hostage rescue operation, resulting in numerous fatalities among both terrorists and hostages.[5] This event underscores the potential for mass casualty incidents involving the deliberate deployment of these agents, highlighting the need for specialized countermeasures for those who may be on the front lines of such events.

Given this evolving threat landscape, there is a clear need for prophylactic measures to protect military personnel and chemical incident responders who may be required to enter areas contaminated with high-potency opioids. Prophylactic treatment aims to prevent or significantly mitigate the onset of respiratory and nervous system depression that can result from opioid exposure, thereby enabling these individuals to continue performing their critical duties in hazardous environments. This necessitates the availability of readily accessible and easily administrable medical countermeasures that can be deployed prior to or immediately upon potential exposure.

III. The Mission and Scope of the United States Strategic National Stockpile

The statutory foundation for the Strategic National Stockpile (SNS) lies within the Public Health Service Act, which mandates the Secretary of HHS to maintain a stockpile of drugs, vaccines, and other medical supplies to ensure the emergency health security of the United States in the face of bioterrorist attacks or other public health emergencies. This legislation grants broad authority to the HHS Secretary to determine which threats warrant preparation and which medical countermeasures should be stockpiled. A fundamental principle of the SNS is to act as a supplemental resource, augmenting the medical supplies available at the state and local levels during times of crisis. The extensive legislative discretion afforded to the HHS Secretary means that the inclusion of countermeasures like prophylactic opioid antagonists is permissible if deemed essential for safeguarding national health security. The potential for high-potency opioids to be employed in attacks could reasonably lead the Secretary to prioritize the stockpiling of preventative treatments for such scenarios.

Operationally, the SNS comprises several key components designed to facilitate rapid and

effective responses to various public health emergencies. The 12-Hour Push Packages are a critical element, consisting of pre-packaged, broad-spectrum medical supplies intended for swift deployment within 12 hours of a federal decision to utilize the stockpile. These packages contain a range of essential items, including oral and intravenous antibiotics, emergency medications, intravenous fluids and administration kits, airway management equipment, and ventilators. Another component is the Managed Inventory (MI), which involves medical materiel maintained by vendor partners under the direction of the Centers for Disease Control and Prevention (CDC). These resources can be accessed and tailored to meet the specific requirements of a particular incident.[28] The CHEMPACK Program represents a forward-leaning strategy for chemical threat preparedness, involving the strategic placement of chemical agent antidotes, primarily atropine and pralidoxime, in secure locations to enable rapid response to chemical exposures . While the primary focus of CHEMPACK has historically been on nerve agents , the underlying principle of pre-positioning critical antidotes for rapid deployment could serve as a model for opioid countermeasures. Additionally, the SNS includes Federal Medical Stations (FMS), which are rapidly deployable caches of beds, medical supplies, and medicines designed to provide temporary medical care for individuals affected by a public health emergency.[29] Finally, User-Managed Inventory refers to medical supplies pre-positioned at the state and local levels to enhance local preparedness.[28] While the CHEMPACK program demonstrates the value of forward-positioned antidotes, the current contents of the 12-hour push packages, being designed for a broad range of threats, may not specifically include prophylactic opioid treatments, potentially indicating a gap in current preparedness for this specific scenario.[35]

Accessing materiel from the SNS typically involves a request initiated by state, local, tribal, and territorial (SLTT) health jurisdictions based on a demonstrated need for resources that exceed local capabilities. The decision to deploy SNS assets rests with the HHS Secretary, often following coordination with the Administration for Strategic Preparedness and Response (ASPR) Regional Emergency Coordinators (RECs) and the HHS Secretary's Operations Center (SOC).[28] For 12-hour push packages, delivery to the requesting jurisdiction generally occurs within 12 hours of the deployment decision.[18] This reliance on requests from SLTT jurisdictions might present a logistical challenge for the proactive deployment of prophylactic treatments specifically intended for specialized personnel such as military personnel and federal responders, unless specific protocols or pre-approved arrangements are established to address their unique operational requirements.

IV. Medical Countermeasures in the SNS for Opioid-Induced Respiratory and Nervous System Depression

The Strategic National Stockpile (SNS) maintains a comprehensive formulary of medical countermeasures designed to address a wide range of public health threats, including a broad spectrum of medications such as antibiotics, antidotes, and antitoxins. Within this formulary, naloxone stands as the primary medication for reversing the potentially life-threatening effects of

opioid overdose. Standard formulations of naloxone, including both injectable solutions and user-friendly nasal spray options, are readily available through various channels, including the SNS. While the presence of naloxone in the SNS underscores its importance as a general opioid antagonist for public health emergencies, its inclusion in the standard formulary does not inherently address the specific requirements of military personnel and chemical incident responders who may need prophylactic treatment against exposure to high-potency opioids. The unique operational contexts and the need for pre-exposure long-acting protection in these scenarios necessitate a closer examination of specialized countermeasures.

A significant development in this area is the 10 mg naloxone auto-injector, which has been specifically developed and approved for use by military personnel and chemical incident responders. This product holds indications for both the emergency treatment of suspected high-potency opioid exposure and the temporary prophylaxis of respiratory and/or central nervous system depression in individuals entering potentially contaminated areas. The higher intramuscular dose of 10 mg may offer enhanced effectiveness in reversing the effects of ultra-potent opioids like fentanyl analogues. The Department of Defense (DoD) has expressed a preference for auto-injector formulations due to their ease of administration, particularly when personnel are wearing personal protective equipment. The 10 mg naloxone auto-injector received FDA approval in February 2022 and has been assigned a NATO Stock Number (NSN 6505-01-699-8878), signifying its adoption by military organizations. The specific development and approval of this product for this particular indication strongly suggest its inclusion in the SNS, at least for use by military and federal response agencies.

Beyond naloxone, other potential countermeasures for opioid-induced depression are being explored and, in some cases, have been procured by government agencies. Nalmefene (marketed as OPVEE) is a nasal spray opioid antagonist with a longer duration of action compared to naloxone and is specifically indicated for reversing overdoses from synthetic opioids . The Biomedical Advanced Research and Development Authority (BARDA) has recently procured OPVEE, primarily for use in community overdose situations and potential mass casualty events.[13] Ongoing research efforts are also focused on developing other therapeutic agents like thyrotropin releasing hormone (TRH) and innovative biohybrid materials are under investigation as potential medical countermeasures for opioid toxicity.

TH104, is under development for the prophylaxis of respiratory and/or nervous system depression in military personnel and chemical incident responders. This product has a longer half-life compared to the naloxone auto-injector, potentially offering a more sustained prophylactic effect. Furthermore, TH104 utilizes a buccal film delivery system, which may offer a more convenient route of administration compared to the nalmefene nasal spray, particularly in situations where wearing personal protective equipment might complicate the use of nasal sprays. The development of TH104 suggests a continued focus on identifying and developing improved prophylactic solutions for this critical need.

While naloxone, particularly the 10 mg auto-injector, appears to be the primary focus for the specific prophylactic needs of military personnel and chemical incident responders, BARDA's procurement of nalmefene indicates a broader government strategy to enhance preparedness against opioid threats, which could potentially extend to supporting responders in large-scale incidents.[13] The continued research into novel opioid antagonists, including investigational products like TH104, suggests a future landscape with more advanced options for both treatment and prophylaxis.

V. Government Procurement and Stockpiling of Relevant Medical Countermeasures by HHS and BARDA

The Biomedical Advanced Research and Development Authority (BARDA) plays a crucial role in the United States' preparedness for public health emergencies by facilitating the development and availability of essential medical countermeasures (MCMs). BARDA achieves this mission through unique public-private partnerships aimed at fostering innovation and translating scientific advancements into practical medical solutions. In response to the escalating opioid crisis and the potential for mass casualty events involving synthetic opioids, BARDA has recently procured nalmefene nasal spray (OPVEE).[13] This acquisition, with an initial order valued at $8.7 million[13], is intended to supplement local supplies of emergency opioid overdose medications for use by emergency rooms, ambulances, and other first responders in the event of medical countermeasure shortages during an emergency response.[13] This action by BARDA demonstrates a government commitment to stockpiling advanced opioid antagonists beyond traditional naloxone, potentially broadening the scope of available treatments for responders in mass poisoning scenarios in the future.[13]

The Department of Defense (DoD) has taken a direct and proactive approach to addressing the specific threat posed by high-potency opioids to military personnel. Recognizing the need for a specialized countermeasure, the DoD identified a requirement for a 10 mg naloxone auto-injector for use by service members who may encounter these agents in military operations or terrorist attacks. To fulfill this need, the DoD partnered with the pharmaceutical company Kaléo to develop the Rapid Opioid Countermeasure System (ROCS). This collaborative effort culminated in the FDA approval of the 10 mg naloxone auto-injector in February 2022. Subsequently, in September 2022, the DoD awarded its first supply contract to Kaléo for the procurement of up to 788,000 units of this specialized auto-injector. This initial contract was followed by a follow-on production agreement awarded in August 2022[42], further solidifying the DoD's commitment to securing this critical medical countermeasure. The 10 mg naloxone auto-injector is now available to military units through the Defense Logistics Agency (DLA) Prime Vendor program , ensuring efficient access for deployed personnel. The DoD's direct involvement in the development and procurement of this specific countermeasure signifies a dedicated market for prophylactic opioid treatments within the military and for chemical incident responders operating under its authority. The significant volume of the initial contract underscores the scale of this investment in

preparedness .

The Administration for Strategic Preparedness and Response (ASPR) oversees the Strategic National Stockpile (SNS) and plays a central role in national health security.[47] The FY2024 budget request for ASPR prioritizes funding for the sustainment of existing medical countermeasure product lines and the procurement of products previously supported by BARDA that lack a significant commercial market. While this indicates a continued focus on maintaining and replenishing the SNS, the provided snippets do not explicitly mention large-scale stockpiling of the 10 mg naloxone auto-injector by HHS/ASPR. The exception is BARDA's procurement of OPVEE, which is intended for broader emergency response scenarios.[13] This suggests that the procurement of the 10 mg naloxone auto-injector might be primarily managed independently by the DoD to meet its specific operational requirements. It remains possible that HHS/ASPR may plan to stockpile this product within the SNS for broader use by civilian chemical incident responders or to support military needs during domestic incidents, but this is not explicitly detailed in the available information. BARDA's role appears to be focused on the advanced development and initial procurement of innovative countermeasures, potentially paving the way for their inclusion in the SNS at a later stage.

VI. Potential Threat Scenarios Involving High-Potency Opioids Requiring Prophylaxis

Several potential threat scenarios involving high-potency opioids could necessitate the prophylactic use of medical countermeasures for military personnel and chemical incident responders. Military operations conducted in environments where chemical weapons, including highly potent opioids, might be deployed represent a primary concern. In such situations, it is crucial for troops to maintain operational readiness and remain ambulatory even after potential exposure to these agents.[5] The historical use of aerosolized synthetic opioids by Russian special forces in a hostage situation[5] serves as a stark reminder of the potential tactics that adversaries might employ. Prophylactic treatment in these contexts would be vital for preserving the effectiveness and safety of military personnel.

Chemical incident response operations also present scenarios where prophylactic measures would be essential. First responders, including hazardous materials (HAZMAT) teams, emergency medical services (EMS) personnel, and law enforcement officers, may be required to enter areas contaminated with high-potency opioids, whether the contamination is accidental or the result of an intentional release. In these hazardous environments, the protection afforded by prophylactic opioid antagonists would be critical to ensure the safety and operational capacity of these responders, allowing them to effectively conduct rescue and containment efforts.[5]

Furthermore, the potential for terrorist attacks or other mass casualty events involving the intentional release of high-potency opioids in public areas cannot be overlooked. While widespread prophylactic treatment for the general public may not be feasible, ensuring adequate protection for responders in contaminated zones is crucial. This highlights the need for sufficient

stockpiles of appropriate medical countermeasures for those who will be involved in the immediate response and rescue operations following such an event.

VII. Estimated Number of Military Personnel and Chemical Incident Responders Potentially Requiring Prophylaxis

Estimating the precise number of military personnel who might require prophylactic treatment for potential exposure to high-potency opioids is challenging due to the classified nature of military deployments and threat assessments. However, it is likely that the focus would be on specialized units, such as Chemical, Biological, Radiological, and Nuclear (CBRN) response teams and special operations forces, as well as personnel deployed in regions considered to be at higher risk of chemical attacks.[7] The Department of Defense's procurement of up to 788,000 units of the 10 mg naloxone auto-injector provides an indicator of the scale of their preparedness efforts. While this quantity likely includes doses intended for both prophylactic use and emergency treatment, it sets an upper bound on the number of individuals the DoD anticipates needing this countermeasure. This procurement volume suggests that a considerable number of military personnel are considered potential recipients, underscoring the importance the DoD places on addressing this threat.

The category of chemical incident responders who might require this type of prophylaxis includes a diverse group of professionals at the federal, state, and local levels. This would encompass HAZMAT teams, specialized EMS units trained in chemical incident response, and potentially law enforcement personnel who may be among the first to enter a contaminated area. While the exact number of federal-level responders who would require prophylactic treatment is likely smaller than the number of potentially affected military personnel, it is still a significant figure. The fact that the FDA label for the 10 mg naloxone auto-injector specifically includes "chemical incident responders" as an intended user group indicates a recognized need for this countermeasure beyond the military. However, the available snippets do not provide specific numbers for this cohort, highlighting an area where further investigation into federal emergency response structures and protocols would be necessary to obtain a more precise estimate of the potential market size.

VIII. Analysis of Past and Planned Acquisitions by the SNS to Estimate Market Size

Given the specific indication for temporary prophylaxis of opioid-induced depression in military personnel and chemical incident responders, the Department of Defense's (DoD) acquisition of the 10 mg naloxone auto-injector serves as the most direct indicator of the current market size for this particular medical countermeasure. The initial contract awarded to Kaléo for the manufacture and delivery of up to 788,000 units represents a substantial market volume for a product targeted at this specific need. While the precise monetary value of this contract is not explicitly stated in the provided snippets, information regarding other government contracts awarded to Kaléo[36] suggests that this procurement likely involves a significant financial

investment. This procurement directly addresses the need for both emergency treatment and temporary prophylaxis against high-potency opioids for military personnel and designated chemical incident responders.

BARDA's recent procurement of OPVEE (nalmefene) nasal spray, with an initial order of $8.7 million[13], represents another facet of the government's investment in opioid countermeasures. While OPVEE is primarily indicated for the emergency treatment of known or suspected opioid overdose, including those induced by synthetic opioids[13], its longer duration of action compared to naloxone[41] could potentially make it a valuable asset in mass casualty scenarios where a prolonged opioid effect is anticipated, possibly including situations where responders might benefit from a longer window of protection. Therefore, BARDA's acquisition signifies a related but distinct market segment focused on broader emergency response capabilities for opioid overdoses, which could indirectly support the prophylactic needs of some responders in specific large-scale incidents.[13]

Notably, the provided research material does not contain explicit evidence of large-scale procurements of the 10mg naloxone auto-injector by HHS/ASPR or the SNS specifically for civilian chemical incident responders. This absence of direct procurement data could suggest several possibilities: that the DoD is managing the procurement and distribution of this specific product primarily for its own needs and for federal responders working directly under its authority; or that the SNS may have plans for future stockpiling of this countermeasure for civilian responders, but these plans have not yet been publicly documented in the sources reviewed. It is also possible that the SNS relies on standard naloxone formulations for broader civilian response scenarios, with the 10 mg auto-injector being considered a specialized asset managed by the DoD. The current information indicates that the DoD's procurement activities are the primary driver of the identified market for this specific prophylactic opioid countermeasure.

IX. Review of Existing Market Research on Medical Countermeasures for Opioid Exposure and Chemical Threats in the US Government Sector

A review of the provided research material indicates a limited availability of specific market research reports directly addressing the niche market of prophylactic opioid countermeasures for military personnel and chemical incident responders within the US government sector. General market research reports on opioids, such as the one detailing the global opioids market[52], tend to focus on the broader pharmaceutical market for pain management, cough treatment, and addiction therapies, rather than the specific area of government stockpiling of medical countermeasures for chemical threats. While market research analyses covering the broader landscape of medical countermeasures may exist, these were not included in the provided snippets. This suggests that the specific market segment in question may not be extensively covered by publicly available commercial market research.

Government reports and budget documents from agencies like HHS and the DoD provide valuable insights into the overall financial resources allocated to medical countermeasures and public health preparedness. Documents such as the PHEMCE Multi-Year Budget (MYB)[53] forecast the funding required for the research, development, procurement, and stockpiling of civilian medical countermeasures over a multi-year period. However, these high-level budgetary documents typically do not provide granular details on the specific quantities or values of individual product acquisitions, such as the 10 mg naloxone auto-injector. Therefore, while these documents offer a broader context of government spending in this area, they do not directly quantify the market size for the specific indication under analysis.

In contrast, trade publications and industry news articles prove to be crucial sources for tracking specific government procurement activities and market developments within this specialized domain. News reports often announce contract awards, FDA approvals, and other key milestones related to the development and acquisition of medical countermeasures, including the 10 mg naloxone auto-injector. These sources provide the most specific and timely information regarding the government's efforts to procure and stockpile these specialized treatments for military personnel and chemical incident responders.

X. Conclusion: Market Outlook and Potential Opportunities

The analysis of the provided research material indicates that the current market for temporary prophylaxis of opioid-induced respiratory and nervous system depression within the US government sector, specifically targeting military personnel and chemical incident responders, is significantly shaped by the Department of Defense's (DoD) procurement of the 10 mg naloxone auto-injector. The initial contract for up to 788,000 units represents a substantial initial market size for this specialized medical countermeasure. The role of the SNS, managed by HHS/ASPR, in stockpiling this specific product for civilian responders is less clearly defined in the available information, suggesting that the current market within the SNS for this particular indication might be smaller or not yet fully established. BARDA's procurement of nalmefene highlights a broader government interest in advanced opioid countermeasures for emergency response scenarios, which could indirectly benefit responders in mass casualty events.[13] Notably, there appears to be a limited amount of specific market research publicly available that directly focuses on this niche area of government procurement.

Looking ahead, continued procurement of the 10 mg naloxone auto-injector by the DoD is anticipated to meet the ongoing needs of military personnel . The emergence of products under development like TH104, with potentially superior pharmacokinetic and administration profiles, could introduce future competition or provide alternative solutions for this indication. There is also a potential for increased inclusion of specialized countermeasures in the SNS formulary to equip federal civilian responders who may face similar threats . The future growth of this market will likely be influenced by evolving threat assessments related to the use of high-potency opioids and the development of new, longer-acting prophylactic opioid antagonists that could

offer enhanced protection .

These market dynamics present several potential opportunities. For pharmaceutical companies, there is a clear opportunity to supply the 10 mg naloxone auto-injector to the DoD and potentially to HHS/ASPR for the SNS. Furthermore, the ongoing need for improved opioid countermeasures suggests opportunities for companies to invest in the research and development of next-generation prophylactic opioid antagonists with enhanced efficacy and duration of action, such as buccal film formulations like TH104. Finally, for policymakers, it is crucial to continuously evaluate the adequacy of current stockpiles of these specialized countermeasures and to consider strategies for broader distribution to all relevant responder communities to ensure national preparedness against the evolving threat of high-potency opioids .

Key Valuable Tables:

Table 1: DoD Procurement of Naloxone Auto-Injector 10mg

Data Point	Details
Contract Award Date	September 21, 2022[11]
Awarding Agency	Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)
Contractor	Kaléo, Inc.[11]
Number of Units	Up to 788,000[11]
Contract Value	Not explicitly stated in provided snippets
Purpose	Emergency Treatment and Temporary Prophylaxis against High-Potency Opioids

Table 2: Key Characteristics of Opioid Antagonists Relevant to Prophylaxis

Characteristic	Naloxone (Auto-injector 10 mg)	Nalmefene (OPVEE Nasal Spray)	TH104 (Investigational)
Formulation(s)	Auto-injector (10mg IM)	Nasal Spray	Buccal Film
Indication	Emergency Treatment & Temporary Prophylaxis of Opioid-Induced Depression (for military/responders)	Emergency Treatment of Known or Suspected Opioid Overdose	Temporary Prophylaxis of Opioid-Induced Depression (for military/responders)
Onset of Action	Rapid (intramuscular)	Rapid (nasal)	Not specified in provided information
Duration of Action	30-90 minutes (may require repeat doses)[58]	>10 hours[41]	Longer half-life than naloxone auto-injector
Availability in SNS	Probable for DoD/Federal Responders; Less clear for broader SNS	Procured by BARDA; Potential for broader SNS inclusion	Investigational

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