Department of HHS Restructure: Reform or Ruin?

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When the welfare of many calls for a strong, national healthcare system that is universally accessible, cost effective, and streamlined, should current systems continue to strive yet malfunction? In recent years, the United States's Department of Health and Human Services (HHS) has evolved into a direct presentation of an administration that cannot effectively reconcile its diverse responsibilities to deliver the needs put forward by the public. The abundant issues regarding the HHS's administration have universally characterized the department for years, both internationally and within the US; with citizens viewing the impacts of the administration's costs, internal discrepancies, etc. The HHS's characterization was only amplified on March 27th, 2025 following the agency's newly announced initiative to entirely alter its foundation. Given the HHS's complex and often conflicting mandates, encompassing everything from regulating pharmaceutical drugs to managing large entitlement programs like Medicare and Medicaid, the department faces many issues, like balancing competing directives and political pressures. As this new plan towards reconstruction is put forth, these previously significant issues become bolstered beyond the point of negligible.

The HHS's new plan will play a significant role in simply perpetuating the department's shortcomings, notably regulatory concerns. One of the reconstruction plan's main counterparts introduced the mass removal of employment—with their initial 82,000 full-time workers being reduced to 62,000. While the HHS claims that its workforce reduction strategies will be executed yet maintain essential services, this promise only proves unfeasible under a realistic lens. For instance, cuts to the FDA (Food and Drug Administration within the HHS) staff hinders the agency's capacity for properly reviewing and approving new drugs and medical devices.

Decreased staff would also play a role in compromising the rigor of safety assessments, and in turn, putting patients at a higher risk.

In further regards to the FDA, weakened post-market surveillance is an inevitable effect of the HHS's restructuring. To elaborate, after the FDA has approved any new medical equipment or drug, it remains essential to continue monitoring its safety and effectiveness in real-world settings, as rudimentary clinical trials don't always account for all potential risks or long-term impacts. Hence, post-market surveillance is utilized to collect data on adverse events, tracking patient outcomes, and identifying any safety signals that may arise. However, even prior to the dismantling of the HHS in favor of a restructured system, the department has featured integral flaws within their post-surveillance strategies.

A renowned exhibition of the FDA's inefficiency in the heavily relied on post-market surveillance was The Vioxx (Rofecoxib) Case in 2004. This well-known case involved a pain medication that came to be linked with increased risk of cardiovascular events (like heart attacks and strokes). Ultimately hindering the physical health of more than 80 million patients who had already taken the drug before it was withdrawn from the market, critics blamed the FDA, contending that the administration's post-market surveillance system was too slow and ineffective to detect the safety signal. What was hastily erected from this pain medication's impacts on patients came to be the largest prescription-drug withdrawal in history, despite the abundance of warning signs the FDA and HHS as a whole were presented with. What serves as an even greater display of the FDA's incapacity to adeptly facilitate inspections of drugs and medical devices was the department's decision to wait two years until conducting a meeting regarding the cardiovascular risks associated with rofecoxib. The drug was introduced to the

market in 1999, the meeting was conducted in 2001 — however, the information it yielded further bolstered the FDA's dire need for more efficient post-surveillance tests.

Statistics gleaned from the meeting revealed that the FDA had missed many opportunities to ensure the safety of rofecoxib before making it available to the public. An analysis by Eric J. Topol, from the Cleveland Clinic Foundation utilized the known association between coxibs (like rofecoxib) and arterial inflammation (in correlation with other cardiovascular ailments) to highlight another shortcoming of the HHS. He states, on the basis of his analysis, that a trial specifically designed to identify and mitigate the risks of heart disease/attack before the widespread use and production of rofecoxib "would have prospectively determined the incidence of cardiovascular events, whose possible association with coxib treatment had not been anticipated in the early and pivotal trials of these drugs." This quote alone, as well as the section of Topol's analysis that accompanies it, portrays a significant delay in addressing rofecoxib post-approval related concerns, and notably points to failures in the FDA's pre-market testing requirements.

Beyond the case of rofecoxib alone, other important drug administrations via the FDA and HHS as a whole, beginning as early as the 1990's and remaining relevant to this day (especially in light of the new restructures in place) include the Opioid Crisis — a complex and ongoing public health emergency within the United States. To elucidate, in the late 1990s, pharmaceutical companies aggressively marketed painkillers, with claims that they were completely safe and non-addictive. Doctors henceforth began prescribing these medications more liberally, sparking a surge in opioid prescriptions. In the mid 2000s to early 2010s, restrictions on opioid prescriptions finally began to arise as a result of opioid addiction rates surging. Although regulatory actions were hastily adopted for the good of the public, they only

led to the increased use of illicit opioids (specifically heroin) which were cheaper and now more readily available. This issue remains structural in present-day drug matters, as the utilization and production of synthetic opioids like fentanyl has dramatically increased. Subsequent data (from the Centers for Disease Control and Prevention - CDC) comes to show that Opioid overdoses remain a leading cause of death in the U.S.

The FDA was ultimately deemed responsible for the mass opioid usage that arose within the last couple decades, considering its initial approval of the highly addictive opioids, and its transparent failure in monitoring their distribution. Many critics were led to believe (with reasonable suspicion) that the department prioritized the interests of pharmaceutical companies over the public health; these accusations led to the agency's arguably perfunctory steps to finally overlook the production of opioids. However, these measures are viewed by many as holding too little of an impact, as well as executed too late.

The reasons for accusations of inefficiency and effectiveness for these new measures via critics are rooted within the logistics of these strategies, and their foundational discrepancies. For instance, the REMS solution (Risk Evaluation and Mitigation Strategies) — implemented by the FDA, featuring programs that require manufacturers to provide education to healthcare providers/patients about the risks of opioids. While the REMS program outwardly appears to be a feasible and secure solution to the proceeding opioid crisis, the system, in truth, proves overly complex and burdensome to execute. This directly leads to more inconsistencies within the FDA and HHS as a whole, as certain manufacturers choose to abide by the REMS regulations, and others don't because of the difficulties it fosters. REMS, being an education-based initiative, holds little to no true influence on the physical opioid market, in terms of availability; with opioids still remaining readily accessible for mass production and unprecedented use.

Even after accounting for the ultimate incapability of the REMS solution, those that follow it among the HHS's new plans prove even more feeble in addressing the opioid crisis and other public health concerns. Eminently basic solutions, including advisory committee meetings and public hearings on the opioids crisis, as well as essentially negligible labelling changes and black box warnings prove entirely ineffective, and even inefficient to execute to begin with. While stronger warnings pushed out to the public regarding drug and opioid use are necessary, product labels have long proved unworkable, because many addicts disregard them entirely. In terms of advisory committee check-ups, slow and often bureaucratic meetings tend to delay meaningful action, rather than pushing towards it as necessary. Furthermore, it's easy for critics to continually argue that the FDA has been too responsive to industry influence within these meetings, hence further perpetuating public health issues and the opioid crisis.

In order for the FDA and HHS as a whole to provide a true public health foundation for the United States, and look after the welfare of nationwide patients, solutions with more prevalence and impact (in contrast to current restructuring efforts) should be readily employed. Investing in community-based prevention and intervention by shifting resources from exclusively clinical interventions to more inclusive programs that address social determinants of health, for instance, would aid the growing public health crisis. To append, focusing on public education initiatives that truly harbor potential for real influence on public drug perception, through the support of local initiatives focused on substance abuse prevention, as well as mental health services (and aided healthy lifestyle promotion) are more effective and tangible than current measures in place. Such an initiative would also oppose the HHS's current trend of downsizing community-level services, further exhibiting their importance and relevance in growing health crises.

Formidable solutions for the HHS's shortcomings, that don't require its essential dissolution and restructure also include strengthening public health data infrastructure, and seeing that proper investments are being made into modernizing public health data systems, to improve real-time surveillance of health trends and emerging threats. Such a solution could also entail enhancing data distribution among federal, state and local agencies to facilitate a more coordinated response to public health emergencies. Focusing on increasing the amount of funding for the CDC, and other data collecting agencies would aid this initiative — among many others that could be implemented in place of the HHS's newly introduced restructure. By effectively moving away from the department's recent downsizing of data collection and analysis capabilities, and instead firmly concentrating on expanding capabilities, in all aspects, the agency would properly provide U.S. citizens and patients with a strong healthcare system that holds true prevalence and impact.

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