DuVal CLIENT ALERT

Passing on Tribal Knowledge of FDA Law

Volume 24
Issue 03

HALTING THE RUNAWAY TRAIN:

United in Opposition to FDA's Wound Dressing Classification

Halting the Runaway Train: United Opposition to FDA's Wound Dressing Classification

INTRODUCTION

On November 29th, 2023, FDA posted a Proposed Rule to Regulations.gov titled "Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes" (the "Proposed Rule"). The open comment period for the Rule was designated to close on February 28, 2024, with 74 total unique comments uploaded to date. In its own summary, FDA states,

> ***"[We] are proposing to classify certain types of wound dressings and liquid wound washes containing antimicrobials and/or other chemicals (unclassified, preamendments devices) as solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes."***

Given DuVal & Associates' dedication to regulatory advice in the medical device industry and regular representation of clients engaged specifically within the wound dressing, wound products, and combination product spaces (Wound Products), ***we filed our objecting comments*** **(found here)** that addresses significant concerns propagated by this Proposed Rule.

Below we have assembled and categorized the comments to the proposed rule found on FDA's website. We encourage you to see the strong opposition to this rule. We give industry a place to comment further. It remains to be seen if FDA is truly interested in these comments or is this a runaway train and the comments are small obstacles to be removed from the tracks or run over.

IN SUMMARY

As more intricately detailed by our full comment, the Proposed Rule attempts to reclassify a class of products that has been de facto classified for decades. It is a well-established family of products. There is no need for classification. We have survived for decades without it. ***The Proposed Rule imposes new stringent requirements on wound product clearances and approvals under the pretext of addressing antimicrobial resistance ("AMR").*** However, these regulations appear to be based on unsubstantiated and exaggerated scientific and

medical concerns regarding the impact of antimicrobial wound products on the microbiota and AMR. While FDA emphasizes its efforts to address AMR, the underlying motive seems to be to take advantage of a perceived AMR crisis to permit a rapid implementation of substantial regulatory changes within the Wound Products sector. This includes proposed changes to the labeling of new and existing products and an attempt to impose as yet undefined special controls that are unnecessary. The attempt to regulate Wound Products is hindered and undermined by

- past administrative proceedings in which FDA's own advisory panels did not agree with FDA to change the regulatory framework,
- a thin (to non-existent) administrative record that does not scientifically or medically support FDA's conclusions (i.e., scientific literature not supportive of the Proposed Rule), and
- decades of existing clearances and marketing with an unremarkable safety record.

Somehow, this has led FDA to leverage the perceived issue of AMR and its effect on the microbiota as a justification to impose new burdensome regulations and retroactive adjustments to the 510(k) program, despite lacking substantiated evidence for such actions.

Why is it that FDA often feels the need to over-regulate quiet, well-known, well-settled, product categories? Is it fiefdom building, a scientific expedition without a destination, a mindless escalation of data requirements, regulatory boredom, or all the above?

Some surmise it is an attempt to collaborate with research-based academia to generate more clinical trials and government grants for a new vista of scientific information to satisfy scientific curiosity and fill the coffers of university research departments. Others believe the rush is to get this done in the event there is a potential change in Presidential Administrations that might not allow this Proposed Rule to proceed, at least not as currently drafted. Whatever the motivation, necessary or unnecessary, or a little of both, this seems to be a solution in search of a problem.

We recognize and appreciate that FDA has a bona fide concern for AMR and its collateral effect on the microbiota, but there is no objective or circumstantial evidence to support such a belief as it relates to Wound Products. We certainly can agree there is a category of Wound Products, impregnated with more serious AMRs, that need to be regulated with Class III PMAs. There is also a category of products containing well-known drugs that can safely remain in the Class II category without adding to the regulatory regime governing them. The purported concern appears to be an artificially manufactured crisis, enabling the imposition of unnecessary regulations and controls on wound products. ***Antimicrobial Wound***

Products actually serve as a solution to AMR by reducing the need for systemic drug use. Yet, FDA persists in proposing additional testing requirements that are unnecessary to the supposed threat posed by these products, which may further complicate the regulatory landscape without addressing the core issues of AMR.

An attempt to implement sweeping regulations for Wound Products based on a speculative hypothesis regarding AMR reflects a broader trend of administrative overreach. Despite industry objections, laid bare in the public comments provided by many organizations and individuals, and the lack of convincing evidence, FDA persists in its endeavor to change the regulatory framework for clearing a Wound Product. The Proposed Rule takes a serious shot at changing the 510(k) program and its reliance on predicates. ***FDA is an administrative agency, not a legislative body.*** If such significant changes are to be made, Congress needs to be involved, and a sturdier scientific justification must be provided, neither of which is currently evident in FDA's proposed rulemaking on this matter.

The approach to addressing the issue at hand is infirm and unlawful from a number of perspectives.

- ***First,*** FDA creates a regulatory fiction by treating wound products as unclassified entities, despite their long-standing de facto classification.
- ***Second,*** FDA's administrative record, largely based on public scientific literature, fails to adequately support the drastic regulatory changes proposed, particularly concerning larger antimicrobial resistance (AMR) and microbiota issues***. It would behoove the government to initiate long-term studies to understand the AMR issue better by considering the everyday use of antimicrobial products in various settings.***
- ***Third,*** the Rule indirectly attempts to alter the 510(k) program by de facto negating the existing process, invalidating labeling for currently cleared devices, and possibly requiring new studies to lawfully promote existing intended use statements. This maneuver undermines the statutory framework and due process associated with 510(k) clearances, as FDA lacks the authority to rescind or alter clearances without substantial cause presenting a clear and present danger to the public. A 510(k) is a legal order and cannot be changed without due process.
- ***Fourth,*** the Proposed Rule imposes unclear requirements on both new and existing 510(k) Wound Products, mandating new clinical data submissions without clear evidence or justification for such drastic changes. This not only places undue burdens on manufacturers but also fails to acknowledge existing products' lawful clearances and safety records. Furthermore, the Rule appears to suggest current labeling for cleared devices must change and subsequent devices will not be able

to inherit the labeling of their chosen predicate. FDA seems intent on taking away currently cleared claims such as "may aid healing" and "may help in wound management."

- ***Fifth,*** FDA's acceptance of the World Health Organization's classification of AMR constitutes an unlawful delegation of authority, given that the WHO lacks jurisdiction and authority within the US governmental framework.
- ***Sixth,*** the Proposed Rule is antithetical to the statutory Least Burdensome requirements imposing unnecessary regulatory burdens without proportional risk assessment, violating both "substantial equivalence" and "minimum necessary" principles.
- ***Finally,*** the potential ramifications of implementing the Proposed Rule include stifling innovation, reducing product availability, and exacerbating the of AMR by limiting the use of antimicrobial Wound Products, ultimately undermining patient care and public health efforts.

CONCLUSION

To conclude, our concern is the Proposed Rule is a solution in search of a problem. It attempts to address the issue of antimicrobial resistance in a precipitous, unsubstantiated, overbroad, and unnecessary manner. Wound Products today are well-known and well-characterized by nearly fifty years of tried-and-true testing and everyday use. ***Ultimately, this Proposed Rule will hamper innovation, reduce product availability, limit options for physicians, and harm patients.*** This is analogous to what has occurred in Europe under the Medical Device Regulations, where unnecessary increased regulatory requirements have caused significant regulatory burden and acute product shortages—a self-inflicted wound created by the government.

Distillation of the Public Comments—Strong Opposition, Will FDA Listen?

We have also conducted a brief review of all the public comments made to the Proposed Rule, with the aim of recognizing how the wound care community has responded to a particular issue. Our goal is to provide a clear and concise evaluation of the community's reaction, which we believe will foster continued discussion by all stakeholders on this topic. ***The results strike a plain picture. Out of the 74 total unique comments uploaded to date, we have classified at least 56 as firm objections to the rule, 14 as objecting to at least a portion of the rule, 2 as only requesting clarification without a distinct stance, and 2 as clear agreements with the rule.***

Significant interest was furnished across the wound care space categorically, with at least 23 Physician/HCP sources, 17 wound care manufacturers, and 11 medical associations providing comments. This includes a comment from the Alliance of Wound Care Stakeholders, whose members include 40 manufacturers, distributors, or suppliers, as well as 22 clinical associations. Members of the Alliance of Wound Care Stakeholders (found ***here***) include 3M Health Care, Medline, Smith+Nephew, Urgo Medical North America, ETS Wound Care, Integra LifeSciences, the American Diabetes Association, the American College of Foot and Ankle Surgeons, and the Wound, Ostomy, and Continence Nurses Society to name a few. As for identifiable trendlines, we note that the cost-prohibitive nature of the approval process, unclear FDA device approval expectations, an unrealistic implementation timeline (6 months), increased rates of burn wound infection, potential increased morbidity and mortality, an increased need for systemic antibiotics, and limited access to necessary products, were all repeatedly cited concerns. For a more intricate breakdown of the comment contents, data, and direct links to each individual comment, click here to view the Google Sheet.

Stance	Count by Stance
Objected to Rule	56
Objected to Portion	14
Only Requested Clarification	2
Agreed with Rule	2
Total:	74

Commenter	Count by Type
Physician/HCP	23
WC Manufacturer	17
Anonymous/Misc.	12
Med. Assoc.	11
Industry	11
Total:	74

Discussion and feedback are welcomed! Please submit your comments using the link below. We will provide these comments to FDA, the White House, and Congress.

SUBMIT COMMENTS

DuVal & Associates

Drug, Device and Food Law

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations for products at all stages of the product life cycle. Our clientele includes companies that market and manufacture medical devices, pharmaceuticals, biologics, nutritional supplements, and foods. Our clients range in size from Global Fortune 500 companies to small start-ups. As one of the only dedicated FDA regulatory law firms in the United States, our mission and absolute focus is providing our clients appropriately aggressive, yet compliant, guidance on any FDA related matter. We pride ourselves not only on our collective legal and business acumen, but also on being responsive to our client's needs and efficient with their resources. DuVal & Associates understands the corporate interaction between departments like regulatory affairs, marketing, sales, legal, quality, and clinical, etc. As former industry managers in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results; while practical, timely advice can help companies succeed.

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