ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

November 17, 2021

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Submitted Electronically to www.regulations.gov

Re: Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry (Docket FDA-2020-D-2307)

To Whom This May Concern:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are submitting the following comments in response to the FDA draft guidance for industry "*Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products*"**.** The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. As such, we have a vested interest in this guidance document. A list of our members can be found at www.woundcarestakeholders.org.

The Alliance has long been a proponent of utilizing Real World Evidence (RWE) – especially in wound care. We demonstrated this in our article "Consensus Principles for Wound Care Research Obtained Using a Delphi Process" (Wound Rep Reg (2012) **20** 284–293 © 2012 Wound Healing Society) where one of our principles are "national or formal wound registries should be developed with real-world data collection." A copy of that article is attached for your review.

We commend the FDA for creating this draft guidance document. The Alliance believes that it is an appropriate pathway and a good beginning. We also commend the Agency's commitment to utilize RWE as a "top programmatic priority" in the regulatory process and are supportive for the use of data from registries, claims, and electronic health records to support the evaluation of drugs and biologics.

Patients with chronic wounds have serious co-morbid conditions that distinguish them from the patients of wound care RCTs. Due to the serious co-morbidities that chronic wound care patients have most are not eligible for participating in RCTs due to the inclusion/exclusion criteria. Therefore, the use of real world data collection is very important and why the Alliance is supportive of this guidance document.

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In 2005 the US Wound Registry (USWR) was created and it was recognized by CMS as a Qualified Clinical Data Registry in 2014. Registries, such as the USWR are ideal vehicles for providing comparative effectiveness research in wound care because it includes real world patients often excluded from RCTs and reflects actual practice. The USWR evaluated the exclusion criteria of all major randomized controlled trials (RCTs) performed in wound care over a decade (1998-2008). It compared those exclusion criteria with the co-morbid conditions, wound characteristics and medications documented among 3,201 patients in 18 hospital based outpatient wound centers. Its findings were that **approximately 75% of real world patients would have been excluded from every major wound healing RCT that brought new products to market over that decade at the "first pass" (based on wound severity and co-morbid medical conditions) even before study related laboratories or tests would have been performed**.

While the Alliance appreciates and thanks the Agency for issuing this important guidance document, we believe that it would be helpful to add some resources specific to wound care in this guidance document as we continue to try to establish industry standards. As such, we recommend that the Agency reference the following articles in this guidance document:

- Carter, Marissa; Harnessing electronic healthcare data for wound care research: Wound registry analytic guidelines for less-biased analysis. *Wound Rep Reg* (2017). DOI:10.1111/wrr.12565
- Fife, Caroline E., Eckert, Phil M.; Harnessing Electronic Healthcare data for wound care research: Standards for reporting observational registry data obtained directly from electronic health records. *Wound Rep Reg* (2017). DOI:10.1111/wrr.12523

The Alliance appreciates the opportunity to provide the FDA with our comments. If you require additional information or have any questions, please do not hesitate to contact us.

Sincerely,

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