AdvaMed
Advanced Medical Technology Association

1301 Pennsylvania Avenue, NW
Suite 400
Washington, D.C. 20004
P :: 202.783.8700
F :: 202.783.8750
W:: AdvaMed.org

Ida Nassar
Vice President, Assistant General Counsel, Ethics & Compliance
Direct:: 202.434.7252
INassar@advamed.org

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Transmitted by Electronic Mail

Administrator Chiquita Brooks-LaSure
Centers for Medicaid & Medicare Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244
Chiquita.Brooks-LaSure@cms.hhs.gov

Re: Open Payments Reporting and Product Brand Names

Dear Administrator Brooks-LaSure,

The Advanced Medical Technology Association (AdvaMed) represents the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Together, our members develop and manufacture much of the lifesaving and life-enhancing healthcare technology transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies.

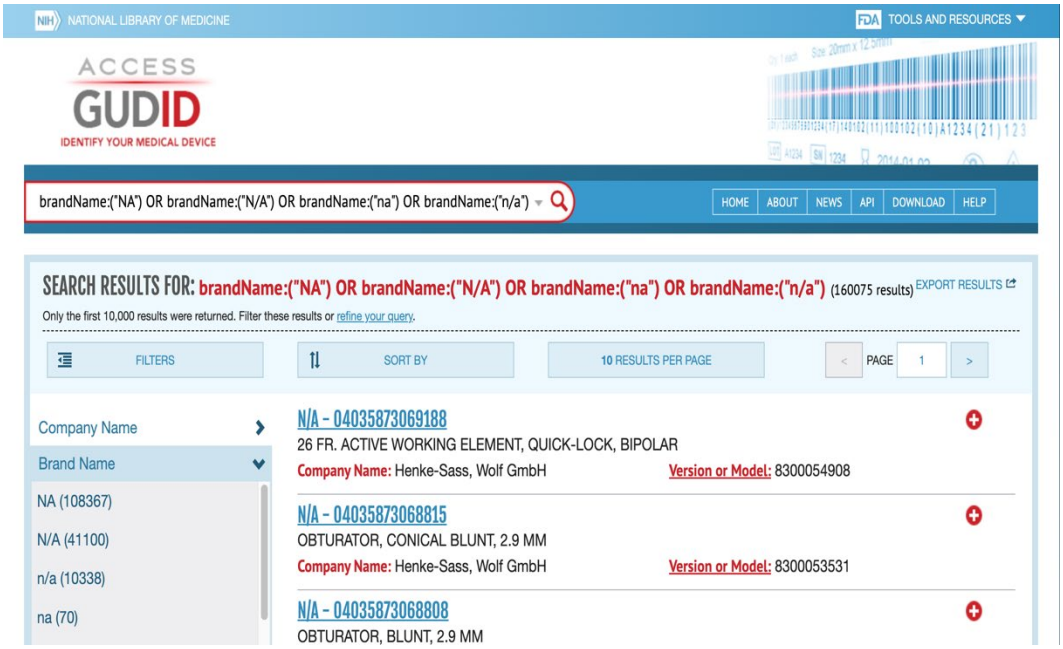
AdvaMed has received inquiries from several members regarding the product brand name information reported on their Open Payments submissions, as required by 42 C.F.R. § 403.904(c)(8)). The concerns arise from letters they received from CMS notifying them that reporting "NA" or "N/A" for the "marketed or brand name" is "invalid." We write to provide insight as to how our members are **properly** reporting consistent with CMS's reference dataset for product brand names. Because our member companies have been properly reporting, we therefore recommend that CMS cease sending letters to medical device manufacturers requesting that they review and revise Open Payments submissions that have, in fact, been properly submitted. Understandably, reviewing and responding to CMS's inquires is unnecessarily consuming time and resources where our members have been effectually following CMS's instructions. We hope this addresses the agency's concerns and would appreciate the opportunity to meet with you to clarify and resolve any remaining issues of concern regarding Open Payments submissions.

In 2022, CMS revised its Open Payment FAQs to add (among others) FAQ Nos. 2020 and 2021, which explain that CMS validates product brand names and identifiers by reference to the Food

and Drug Administration (FDA) Global Unique Device Identification Database Directory (GUDID).[1] CMS's "Resources for Reporting Entities" likewise describe the "reference data" for "medical device and medical supply names" as the "information for all medical device and medical supplies listed in the Food and Drug Administration's Global Unique Device Identification Database Directory (GUDID)."[2] Our member companies therefore rely on the FDA GUDID's "Brand Name" field to comply with 42 C.F.R. § 403.904(c)(8)'s requirements and CMS's related guidance.

Further, the "Brand Name" fields for approximately 160,000 devices included in the FDA GUDID contain "NA," "N/A," "na," or "n/a," as shown in Figure 1 below. Thus, when our members report "NA" (or some derivation thereof) as the product brand name on their Open Payments submissions, it is because that is the product brand name that appears on CMS's approved dataset.

Figure 1: FDA's AccessGUDID Portal [3]



[1] https://www.cms.gov/OpenPayments/Downloads/open-payments-general-faq.pdf
[2] https://www.cms.gov/priorities/key-initiatives/open-payments/resources/reporting-entitities
[3] https://accessgudid.nlm.nih.gov/devices/search?query=brandName:(%22NA%22)%20OR%20brandName:(%22N/A%22)%20OR%20brandName:(%22na%22)%20OR%20brandName:(%22n/a%22)

In light of the above and to conserve time and resources, AdvaMed recommends that CMS cease sending letters to medical device manufacturers requesting that they review and revise Open Payments submissions that have already been properly submitted.

AdvaMed appreciates the difficulty in providing clear, practical guidance to thousands of medical device and pharmaceutical manufacturers and is grateful to CMS for maintaining an open channel for manufacturer feedback. We welcome the opportunity to discuss this matter in more detail.

Thank you for your consideration,

/s/
Ida Nassar, Esq.
Vice President, Assistant General Counsel, Ethics & Compliance

cc: Christopher L. White, Esq., General Counsel & Chief Policy Officer
Open Payments Compliance Team, OPCompliance@cms.hhs.gov