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LETTER TO:

Division of Docket Management
Food and Drug Administration
Department of Health and Human Services
5630 Fisher Lane, Room 1061
Rockville, MD 20852

IN SUPPORT OF CITIZEN PETITION DEEMING NARXCARE SOFTWARE MISBRANDED AND A DANGER TO HEALTH

Our group and writers of youarewithinthenorms.com and Pronto Pharmacy LLC, Tampa Fl are in full support of the Citizen Petition Submitted by the Center for U.S. Policy to request the Commissioner of the U.S. Food and Drug Administration ("FDA") to deem the Bamboo Health ("Bamboo") NarxCare software a misbranded device and take administrative action to prevent serious, adverse health consequences and death. We further demand the immediate removal of this dangerous software from all healthcare systems.

Specifically, The Petitioner asks FDA to:

(1) deem Bamboo's NarxCare software a misbranded device;

(2) issue a Warning Letter to Bamboo;

(3) commence mandatory recall procedures with respect to the NarxCare software; and

(4) take any other prompt action the agency deems appropriate to prevent serious, adverse health consequences or death.

NarxCare is a clinical decision support ("CDS") software product that meets the definition of a "device" under the FD&C Act. Yet, based on a search of FDA's publicly available databases, it appears that the device's manufacturer, Bamboo, is in violation of several provisions of the Act and its implementing regulations. Specifically, before introducing NarxCare into interstate commerce, Bamboo did not comply with the establishment registration, device listing, or premarket notification requirements set forth in Section 510 of the Act.

FDA MUST REMOVE AND BAND NARXCARE

When there is a violation of the Federal Food, Drug and Cosmetic Act, the FDA may, depending on the nature of the violation, give individuals and firms an opportunity to make voluntary and prompt corrections by taking an advisory action. NARXCARE is a danger to healthcare delivery and must be removed

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