February 6, 2018

Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Docket No. FDA-2017-D-6569 for "Clinical and Patient Decision Support Software; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

Dear Commissioner Gottlieb:

Health IT Now (HITN) appreciates the opportunity to comment on the draft guidance entitled *Clinical and Patient Decision Support Software.* HITN is a diverse coalition of health care providers, patient advocates, consumers, employers, and payers who support the adoption and use of health IT to improve health outcomes and lower costs.

HITN is a strong supporter of a risk-based regulatory framework for health software and worked diligently with stakeholders and policymakers to help craft the language in Section 3060 of the *21st Century Cures Act.* We believe that the draft guidance is aligned with Congressional intent and appropriately adopts the risk-based framework called for in the law for clinical decision support software.

We are, however, concerned with lines 228-231 of the draft guidance, which establishes that a practitioner would be unable to independently evaluate the basis of a recommendation if the recommendation were based on non-public information. Sec. 3060(1)(E)(iii) of *Cures* states that health software that enables a health care professional to "independently review the basis for such recommendations that such software presents" shall not be included in the definition of a medical device under the Food, Drug, and Cosmetic Act. With this language, Congress intended to prohibit the exclusion of so-called "black box" software that does not provide transparency in the data that goes into software algorithms. They did not intend to establish a bar that the data must be publicly available. We request that the FDA amend this language to reflect that the information should be available to the healthcare professional instead of publicly available.

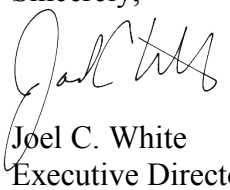
Similarly, we are concerned with one of the examples of CDS and other software functions for health care professionals that remain devices. The example beginning at line 325 of the draft guidance sets a standard that the algorithm used in the software product must be disclosed to the user. Again, we believe that it was Congress' intent that the data be transparent to the user, not the algorithms into which the data are entered. We request FDA amend this example to reflect transparency of data, not of the algorithm itself.

We also note that throughout all of the examples laid out in the document, there is a reliance on information from clinical practice guidelines or other reference information. However, we believe it is important to recognize the growing inclusion of real-world data in medical decision-making. We request

that the guidance document be updated to reflect that many CDS tools are, and more will be in the future, incorporating real-world data into their functions.

We appreciate the FDA's work to advance and support digital health innovation. We look forward to continuing to work together to establish a clear risk-based regulatory framework for digital technology.

Sincerely,



Joel C. White
Executive Director