International Neuromodulation Society Statement on FDA Safety Communication

On November 14, 2018, the United States Food and Drug Administration (FDA) issued a safety communication related to the intrathecal pain pumps, bringing everyone's attention to the fact that the pain medications that are used in some of these pumps are not FDA approved for such use. The communication expressed concerns about additional risks arising from the use of non-approved medications and provided specific recommendations to the patients, caregivers and medical professionals for consideration during decision-making on intrathecal drug choice.

The International Neuromodulation Society (INS) promotes and disseminates the science, education, practice and accessibility of all aspects of neuromodulation. For decades, INS has been at the forefront of research and clinical practice, including various aspects of intrathecal drug administration. Among other efforts in this direction, the Polyanalgesic Consensus Conference (PACC) that works under aegis of INS has created a series of guidelines on intrathecal drug delivery for the treatment of pain. These guidelines specifically mention that in the vast majority of clinical situations (about 80%) the medications used for intrathecal pain control are not approved for this use and are therefore administered on an "off-label" basis.

The INS wholeheartedly agrees with the FDA concerns and encourages all parties involved to follow the published recommendations, including the need to review the labeling/approval status for each pump and medication, the awareness of "off-label" status of some medications, their formulations and mixtures, and additional risks related to the medications and devices, the need for consideration and discussion of risks and benefits of each medication choice, and the need for reporting evidence observed or suspected adverse events to the FDA.

Moreover, with the best interest of our patients in mind, the INS recognizes that in many clinical situations an exclusive use of approved medications cannot provide the desired degree of pain relief and therefore additional efforts are needed to pursue regulatory approval for additional medications and their mixtures, particularly those recommended by PACC guidelines. The INS would encourage the pharmaceutical companies and device manufacturers to seek proper approval for commonly used medications and their combinations to facilitate patient access to safe and effective treatment options.

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