Analysis of The National Medical Registry Device aka (RFID Chip) in Several Bills & Health Care Reform - (known as Obamacare)

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To: General Public & The American People

Say NO! to an enforced - National Medical Registry Device aka Class II and Class III Device (RFID Chip) in the Health Care Reform and In various Bills Presented in Congress (also known as Obamacare)

The National Medical Registry - Class II and Class III Devices, also known as (Unique Device Identification System). Presented in Several Bills of Government, such as H.R 3962 and H.R 3200 also know as Obamacare.

As Government established by LAW that all Americans must have Healthcare, what is not being addressed as to the many who are concerned, is that such care comes with the use of a device that will be IMPLEMENTED in a RFID Chip, also described as a Class II and Class III Device. Such, will allow access to all our Financial, Medical, Immigration Status, Crime and all other information needed as The Secretary of State, seems fit.

HERE IS A COPY OF THE BILL:: H.R.3962 - Affordable Health Care for America Act

(Introduced in House - NOT PASSED)

SEC. 2571. NATIONAL MEDICAL DEVICE REGISTRY.(a) Registry (1) IN GENERAL- Section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) is amended(A) by re-designating subsection (g) as subsection (h); and(B) by inserting after subsection (f) the following:National Medical Device Registry(g)(1)(A) The Secretary shall establish a national medical device registry (in this subsection referred to as the `registry') to facilitate analysis of postmarked safety and outcomes data on each covered device.(B) In this subsection, the term `covered device'--(i) shall include each class III device; and(ii) may include, as the Secretary determines appropriate and specifies in regulation, a class II device that is life-supporting or life-sustaining.(C) Notwithstanding sub paragraph (B)(i), the Secretary may by order exempt a class III device from the provisions of this subsection if the Secretary concludes that inclusion of information on the device in the registry will not provide useful information on safety or effectiveness.(2) In developing the registry, the Secretary shall, in consultation with the Commissioner of Food and Drugs, the Administrator of the Centers for Medicare & Medicaid Services, the Administrator of the Agency for Healthcare Research and Quality, the head of the Office of the National Coordinator for Health Information Technology, and the Secretary of Veterans Affairs, determine the best methods for--(A) including in the registry, in a manner consistent with subsection (f), appropriate information to identify each covered device by type, model, and serial number or other unique identifier;(B) validating methods for analyzing patient safety and outcomes data from multiple sources and for linking such data with the information included in the registry as described in sub paragraph (A), including, to the extent feasible, use of--(i) data provided to the Secretary under other provisions of this chapter; and(ii) information from public and private sources identified under paragraph (3);(C) integrating the activities described in this subsection (so as to avoid duplication) with--(i) activities under paragraph (3) of section 505(k) (relating to active postmarked risk identification);(ii) activities under paragraph (4) of section 505(k) (relating to advanced analysis of drug safety data);(iii) other postmarked device surveillance activities of the Secretary authorized by this chapter; and(iv) registries carried out by or for the Agency for Healthcare Research and Quality; and(D) providing public access to the data and analysis collected or developed through the registry in a manner and form that protects patient privacy and proprietary information and is comprehensive, useful, and not misleading to patients, physicians, and scientists.(3)(A) To facilitate analyses of postmarked safety and patient outcomes

for covered devices, the Secretary shall, in collaboration with public, academic, and private entities, develop methods to--(i) obtain access to disparate sources of patient safety and outcomes data, including--(I) Federal health-related electronic data (such as data from the Medicare program under title XVIII of the Social Security Act or from the health systems of the Department of Veterans Affairs);(II) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and(III) other data as the Secretary deems necessary to permit postmarked assessment of device safety and effectiveness; and(ii) link data obtained under clause (i) with information in the registry.(B) In this paragraph, the term `data' refers to information respecting a covered device,including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, electronic health records, and any other data deemed appropriate by the Secretary.(4) The Secretary shall promulgate regulations for establishment and operation of the registry under paragraph (1). Such regulations--(A)(i) in the case of covered devices that are sold on or after the date of the enactment of this subsection, shall require manufacturers of such devices to submit information to the registry, including, for each such device, the type, model, and serial number or, if required under subsection (f), other unique device identifier; and(ii) in the case of covered devices that are sold before such date, may require manufacturers of such devices to submit such information to the registry, if deemed necessary by the Secretary to protect the public health;(B) shall establish procedures--(i) to permit linkage of information submitted pursuant to sub paragraph (A) with patient safety and outcomes data obtained under paragraph (3); and(ii) to permit analyses of linked data;(C) may require covered device manufacturers to submit such other information as is necessary to facilitate postmarked assessments of device safety and effectiveness and notification of device risks;(D) shall establish requirements for regular and timely reports to the Secretary, which shall be included in the registry, concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative safety and outcomes trends; and(E) shall establish procedures to permit public access to the information in the registry in a manner and form that protects patient privacy and proprietary information and is comprehensive, useful, and not misleading to patients, physicians, and scientists.(5)(A) The Secretary shall promulgate final regulations under paragraph (4) not later than 36 months after the date of the enactment of this subsection.(B) Before issuing the notice of proposed rule-making preceding the final regulations described in sub paragraph (A), the Secretary shall hold a public hearing before an advisory committee on the issue of which class II devices to include in the definition of covered devices.(C) The Secretary shall include in any regulation under this subsection an explanation demonstrating that the requirements of such regulation--(i) do not duplicate other Federal requirements; and(ii) do not impose an undue burden on device manufacturers.(6) With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a device under this section (and any release by the Secretary of that report or information), such report or information shall not be construed to reflect necessarily a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or caused or contributed to a death, serious injury, or serious illness.(7) To carry out this subsection, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2011 and 2012.'.(2) EFFECTIVE DATE- The Secretary of Health and Human Services shall establish and begin implementation of the registry under section 519(g) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1), by not later than the date that is 36 months after the date of the enactment of this Act, without regard to whether or not final regulations to establish and operate the registry have been promulgated by such date.(3) CONFORMING AMENDMENT- Section 303(f)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(1)(B)(ii)) is amended by striking `519(g)' and inserting `519(h)'.(b) Electronic Exchange and Use in Certified Electronic Health Records of Unique Device Identifiers-(1) RECOMMENDATIONS- The HIT Policy Committee established under section 3002 of the Public Health Service Act (42 U.S.C. 300jj-12) shall recommend to the head of the Office of the National

Coordinator for Health Information Technology standards, implementation specifications, and certification criteria for the electronic exchange and use in certified electronic health records of a unique device identifier for each covered device (as defined under section 519(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)).(2) STANDARDS, IMPLEMENTATION CRITERIA, AND CERTIFICATION CRITERIA- The Secretary of Health and Human Services, acting through the head of the Office of the National Coordinator for Health Information Technology, shall adopt standards, implementation specifications, and certification criteria for the electronic exchange and use in certified electronic health records of a unique device identifier for each covered device referred to in paragraph (1), if such an identifier is required by section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)) for the device.(c) Unique Device Identification System- The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue proposed regulations to implement section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)) not later than 6 months after the date of the enactment of this Act.