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POLICY & ACTION FROM CONSUMER REPORTS

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Submitted electronically
Dr. Karen DeSalvo, M.D.
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Suite 729D
Washington, D.C. 20201

RE: Federal Health IT Strategic Plan 2015-2020

Dear Dr. DeSalvo:

Consumers Union, the policy and advocacy division of Consumer Reports, appreciates the opportunity to provide input on the *Draft Federal Health IT Strategic Plan 2015-2020*. Health information technology (health IT) has a great potential for accelerating achievement of the Triple Aim of better outcomes, better quality, and lower costs. However, in many ways, we're not there yet. We, therefore, commend the Office of National Coordinator for Health Information Technology (ONC) for its extremely active year in 2014, culminating with this Strategic Plan, and see this as part of a larger conversation around how to improve health care with health IT.

There are many valuable aspects to this Strategic Plan. However, we are struck by deficiencies in areas of most importance to consumers: (1) inclusion of consumers as partners in the delivery of health care, and (2) health data security and patient privacy.

As with health care in general, the success of health IT hinges on provider partnership with consumers, from the design of health IT systems through whether and how the technology is used by consumers alongside their providers. This draft of the Strategic Plan does not go far enough in recognizing and elevating the role of consumers.

We also question the lack of prominence given to data security and patient privacy. Where included, they are on an excessively delayed timeline. We contend that data security and patient privacy should be at the foundation of health IT design. We, therefore, urge ONC to interweave data security and privacy into each of the Goals, as they should be a fundamental underpinning in all health technology.

Our comments on specific sections of the Strategic Plan are shown below.

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Strategic Goals, Objectives, and Strategies

Overall, we support the goals and objectives in this draft, each of which strengthens and advances the health IT system. Additionally, we are pleased that patient safety and "safe use" of health IT both emerge as relevant themes for consumers in several reports issued by ONC.[1]

We support the inclusion of 32 federal departments and agencies within and outside of the U.S. Department of Health and Human Services. This is a departure from prior approaches, which maintained silos of health IT based on agency ownership rather than permitting sharing of overlapping and valuable technology across all sectors. Certainly, there are risks to including such a broad cohort in this strategy, such as bureaucratic complications and agencies lacking "ownership" of issues. Those risks are outweighed by the potential benefits. This new scheme enables agencies to share technology rather than inventing and reinventing them in parallel. In addition, this proposal opens the door for an agency such as the FCC to broaden access to broadband, which could deliver health IT to more areas. However, we would be remiss not to point out that even with the best planning and intentions, the lack of a dedicated funding stream to support health IT initiatives across the agencies makes the prospect of inter-agency collaboration uncertain.

We also applaud the draft's expanded scope of health care services and service providers that need to adopt and use health IT. This definition of "provider" spanning the care continuum[2] expands the conventional definition of health care providers in a manner that serves consumers and their caregivers by recognizing the full spectrum of care. In addition to this expanded definition, we encourage ONC to recognize the contributions of family and non-clinical caregivers. Including these key partners in the health care team would truly maximize the potential of health IT for all consumers.

Finally, we commend ONC for recognizing that "[s]uccessful implementation of the Plan also means that health IT is culturally and linguistically sensitive, safe, accessible for everyone (including those with limited English proficiency or with disabilities), intuitive, functional, and provides a rewarding user experience"[3]. However, none of the implementation strategies mention access to, or use of, health IT in languages other than English, or in alternate formats and integrated with assistive technologies for

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[1] These reports include the jointly issued ONC, Food and Drug Administration, and Federal Communications Commission draft report, the *FDA Safety and Innovation Act Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework*, issued in April in 2014, accessed at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf; and ONC's Health IT Patient Safety Action and Surveillance Plan 2014 Update, accessed at: http://www.healthit.gov/sites/default/files/ONC_HIT_SafetyProgramReport_9-9-14_.pdf. These reports build upon the 2011 ONC-commissioned Institute of Medicine report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, accessed at: http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx

[2] Including "acute and ambulatory care, long-term services and supports, post-acute care, behavioral health, emergency medical services, home health, oral health, and end-stage renal disease dialysis facilities, pharmacies, laboratories, and public health entities".

[3] Page 6.

individuals with disabilities. Having access to health information is only valuable if it is intelligible. We, therefore, strongly urge ONC to clarify *how* linguistic accessibility will be achieved.

Federal Health IT Principles

Respect individual preferences

As currently drafted, this principle appears to be entirely provider-centric, describing respecting individual preferences as something the provider does *for* the consumer. While we support this principle in general, we urge ONC to revise the draft language to reflect the importance of partnering with consumers in identifying those preferences. Further, we strongly suggest ONC include caregivers and families in this principle, as oftentimes they represent the interests and preferences of consumers who are unable to speak for themselves.

Build a culture of electronic health information access and use

We generally support this principle. However, ONC must recognize that the way they build a culture of electronic health information access and use must be different for providers than for consumers. Indeed, successful integration of health IT into the health care system is only possible if consumers are recognized as key stakeholders and their unique needs are addressed. Doing so requires the prioritization of data security and privacy so consumers feel secure having their health records shared digitally. Furthermore, building and sustaining a culture of health information use necessitates that consumers be educated on how and why to use available technology. We therefore also recommend initiatives to increase health IT literacy.

Be a worthy steward of the country's money and trust

We certainly support the principle that ONC should be a worthy steward of the country's money and trust. However, we do not believe that relying on private markets to accomplish important societal objectives and only acting to correct market failures "when necessary" go hand-in-hand with that principle. We, therefore, suggest ONC revise this principle to clarify that while relying on private markets to achieve health IT goals is an element of worthy stewardship of the country's money and trust, ONC and other related federal and state agencies will continue using government regulation to ensure that private initiatives benefit consumers alongside private interests, and are equally available in all jurisdictions.

Federal Health IT Goals

In general, we are concerned with the number of objectives and strategies from the current plan that appear to be excluded from this draft.[4] As consumer advocates, we

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[4] The following strategies from the current plan are not explicitly included in the draft:

find it particularly challenging that Goal IV Objective A, *Engage Individuals with Health IT,* was removed, as well as Goal III Objective B, *Inform Individuals of Their Rights and Increase Transparency Regarding the Uses of Protected Health Information.* Although there is some overlap with the new Goals and Objectives in this draft, we do not believe the current draft completely echoes the consumer-oriented language in the 2011-2015 strategy.

Goal 1: Expand Adoption of Health IT

Objective 1A: Increase the adoption and effective use of health IT products, systems, and services

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Strategy I.C.2: Track disparities and promote health IT that reduces them.

Strategy III.A.1: Promulgate appropriate and enforceable federal policies to protect the privacy and security of health information.

Strategy III.A.2: Enforce existing federal privacy and security laws and maintain consistency with federal policy.

Strategy III.A.3: Encourage the incorporation of privacy and security functionality into health IT.

Strategy III.A.4: Access technical solutions that could support more granular patient choice and data segmentation.

Strategy III.A.5: Identify health IT system security vulnerabilities and develop strategic solutions.

Strategy III.A.6: Identify health IT privacy and security requirements and best practices, and communicate them through health IT programs.

Strategy III.B.1: Inform individuals about their privacy and security rights and how their information may be used and shared.

Strategy III.B.2: Increase transparency regarding the development of policies and standards related to uses and sharing of protected health information.

Strategy III.B.3: Maintain strong breach notification requirements.

Strategy IV.A.1: Listen to individuals and implement health IT policies and programs to meet their priorities.

Strategy IV.A.2: Communicate with individuals openly and spread messages through existing communications networks and dialogues.

Strategy IV.B.1: Through Medicare and Medicaid EHR Incentive Programs, encourage providers to give patients access to their health information in an electronic format.

Strategy IV.B.2: Through federal agencies that deliver or pay for health care, act as a model for sharing information with individuals and make available tools to do so.

Strategy IV.B.3: Establish public policies that foster individual and caregiver access to their health information while protecting privacy and security.

Strategy IV.C.1: Support the development of standards and tools that make EHR technology capable of interacting with consumer health IT and build these requirements for the use of standards and tools into EHR certification.

Strategy IV.C.2: Solicit and integrate patient-generated health information into EHRs and quality measurements.

Strategy IV.C.3: Encourage the use of consumer health IT to more toward patient-centered care.

This objective focuses on increasing the adoption and effective use of health IT products, systems, and services by providers rather than by *all* stakeholders. Successful integration of health IT into the health care system is only possible if consumers use the tools available to them. We, therefore, urge that ONC add the following 3-year outcome in order to measure whether health IT is truly being adopted and used effectively by all stakeholders: *increase the percentage of patients offered online access to their information*.

One of the strategies to increase health IT adoption is to engage other HHS agencies such as the Health Services and Resources Administration (HRSA), Substance Abuse and Mental Health Services Administration, Centers for Disease Control and Prevention, and Administration for Community Living, to promote health IT adoption. These other HHS agencies provide significant federal funding to community health centers, behavioral health programs, health education and disease prevention programs, laboratories, and public health departments as well as a wide range of social service organizations (such as services to older adults through the Administration on Aging within the Administration on Community Living). Except for past funding from HRSA to support EHR adoption among Federally Qualified Health Centers, there has not been dedicated federal funding to support EHR adoption in these other federally-funded health and social service organizations.[5] We believe that these agencies and departments can propel the expansion of health IT by making adoption of health IT requisite in their current payment programs. It is not clear from the draft whether ONC will proactively encourage such direct funding for EHR adoption for each of the federal agencies and departments asked to aid in the expansion of health IT.

Objective 1B: Increase user and market confidence in the safety and safe use of health IT products, systems, and services

We support this objective and suggest including consumers in the design of safe, usable health IT. We also recommend that ONC revise strategy #3 to also encourage the application of health IT literacy in addition to health literacy for the reasons noted above.

Objective 1C: Advance a national communications infrastructure that supports health, safety, and care delivery

The draft appropriately references the important work that other federal departments and agencies, including the Federal Communications Commission (FCC), must still do to expand access to affordable high-speed broadband internet and wireless connectivity for millions of Americans. However, it fails to mention the policy and regulatory steps that could facilitate the use of health IT by both health care providers and consumers, i.e. making certain health-related text messages free to receiving consumers (as has been done by voluntary agreement of all the major phone carriers for the Text4Babies

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[5] There have also been notable investments in EHRs by the Indian Health Services, Department of Defense, and Department of Veterans Affairs. The “Blue Button” initiative is an innovation developed by the Department of Veterans Affairs.

program). We encourage ONC to include such policy and regulatory steps as potential strategies for this objective in the final draft.

Goal 2: Advance Secure and Interoperable Health Information

Objective 2A: Enable individuals, providers, and public health entities to securely send, receive, find and use electronic health information

Interoperability is an important goal but there are no specific strategies to advance support for patient access to health information exchange, or to resolve remaining issues of patient matching and patient indexes.[6] We suggest that ONC include "resolving remaining issues of patient matching and patient indexes" as a strategy. Otherwise, without the ability to accurately match consumers to their health information, it is unlikely that this objective will be achieved.

This objective offers ONC an opportunity to substantiate how it will promote health IT that is "culturally and linguistically sensitive, safe, accessible for everyone (including those with limited English proficiency or with disabilities), intuitive, functional, and provides a rewarding user experience"[7]. To that end, we encourage ONC to add an additional 3-year outcome: access to health information in non-English languages. We also suggest ONC consider consumer input on what constitutes basic, expanded set of health information.

Objective 2C: Protect the privacy and security of health information

Consumers need meaningful control over their health records. That means they must have a right to keep their records private and that they cannot be forced to give up control of their medical information as a condition of treatment. Additionally, it means that proper systems are in place to secure personal health information that consumers have entrusted to their providers.

In 2006, Consumers Union, along with 19 other organizations, established health IT consumer principles[8],. Those principles still apply today:

- Individuals should be able to access their personally identifiable health information conveniently and affordably;
- Individuals should know how their personally identifiable health information may be used and who has access to it;

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[6] See, ONC's *Principles and Strategy for Accelerating Health Information Exchange (*2013), accessed at: http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf and ONC's *Governance Framework for Trusted Electronic Health Information Exchange* (2013), accessed at: http://www.healthit.gov/sites/default/files/GovernanceFrameworkTrustedEHIE_Final.pdf. The governance framework includes a recommendation to "promote inclusive participation and adequate stakeholder representation (especially among patients and patient advocates) in the development of [health information exchange] policies and practices".

[7] Page 6.

[8] Available at http://consumersunion.org/research/health-information-technology-consumer-principles.

- Individuals should have control over whether and how their personally identifiable health information is shared; and
- Systems for electronic health data exchange must protect the integrity, security, privacy and confidentiality of an individual's information.

For more details on those *Principles*, see Appendix.

Given the need for ensuring public trust and the reality of recent widespread breaches of personal information at Target stores last year and at the U.S. Postal Service and at Sony Corporation this year, some breaches of health information are inevitable, despite all best efforts at security. Despite that inevitability, this Strategic Plan fails to fully address policy strategies to enforce corrective actions and remedies for such breaches. Question such as how and when consumers should be notified of a data breach, who will have the burden of securing consumers' data after such a breach, and whether and to whom a fine or penalty will be paid are each relevant questions to which consumers need answers before they can truly trust that health IT offered to them is in their best interest.

Despite strong statements of policy support for individual privacy and security, the plan does not address the issue of reconciling conflicting state (and federal) health privacy and confidentiality laws and regulations. If interoperability is ultimately a nationwide goal, then some statutory and regulatory hurdles, (including potential federal preemption), must be addressed.

Finally, as we explain earlier in this letter, we are concerned by the lack of priority for data security and patient privacy. We strongly urge ONC to accelerate the establishment and implementation of federal policies and technical solutions related to emerging uses of individual electronic health information by shifting that stated Outcome from a 6-year trajectory to a 3-year trajectory. Indeed, we argue in favor of expediting all data security and privacy practices so they are in place before providers and consumers are propelled to adopt new systems.

Goal 3: Strengthen Health Care Delivery

Objective 3A: Improve health care quality, access, and experience through safe, timely, effective, efficient, equitable, and person-centered care

Health literacy has long been an area of concern for consumer advocates because it impacts the entire health care experience for consumers, including medication adherence and health insurance selection and use. We, therefore, commend ONC for recognizing the need to "address the health literacy issues for different individual and caregiver populations so that the technology matches and improves their health management skills".

However, we do not believe that this broad statement constitutes a *strategy* as much as an objective. We therefore recommend that the final draft include an outcome statement that measures consumer health literacy and, separately, details strategies to achieve this new objective, such as making available educational tools for consumers and training providers to inform consumers of the availability of health IT *and how to use it*.

As explained earlier, access to health information in electronic format is only helpful to consumers with adequate technology literacy to access the information and health literacy to understand the diagnosis.

It would also be appropriate in this objective to respond to the continuing digital divide, but ONC failed to do so. This "digital divide" describes how access, and use of, health IT differs based on age, English proficiency, abilities or disabilities, and urban versus rural location. Whether health IT enhances health care and long-term supports and services delivery should not depend on where the consumer falls on the digital spectrum. We therefore suggest that ONC include strategies to ensure that access and usability of health IT recognizes that there is no *one size fits all* solution for all consumers.

Objective 3C: Improve clinical and community services and population health

This objective includes the strategy of "using health IT to streamline eligibility requirements and expedite enrollment processes to facilitate individual's access to preventive and social services." Although agencies including the Administration for Children and Families, Administration for Community Living, and Centers for Disease Control and Prevention are listed as implementers of this strategy, there has been little progress on aligning eligibility requirements for various federal programs, let alone using health IT for enrollment in preventive and social services funded by these other agencies. Significant work needs to be done to establish such "horizontal integration or alignment," while maintaining the highest standards for individual privacy, confidentiality, and security.

We also note that identifying innovative uses of health IT to connect individuals and providers to community resources, social services, and health education programs is on a six-year trajectory. Given the limited scope of this outcome, such a delayed timeline is unacceptable. For such a slow outlook, this outcome should be amended to catalogue and disseminate innovative uses of health IT to connect individuals and providers to community resources and supports. Otherwise, aside from potential funding-related delays, we see no justifiable reason to defer this outcome; Consumers Union recommends it be revised to a 3-year trajectory assuming the budget is available to do so.

Goal 4: Advance the Health and Well-Being of Individuals and Communities

Objective 4A: Empower individual, family, and caregiver health management and engagement

We commend ONC for empowering individual consumers as well as their family members and caregivers. However, the strategies outlined do not adequately address the complexities of the needs for multiple layers of permissions and authentications when family members and caregivers are involved in the health care of an individual. The strategies listed also fail to address the needs of individuals who have lower health literacy, lower computer/technology literacy, speak/read/write primary languages other than English, or have physical or cognitive disabilities or impairments. Similarly, the strategies fail to recognize that family members and caregivers may also lack the health and health IT literacy as well as common language to benefit from health IT. We therefore urge ONC to revise the strategies listed here.

Health IT is evolving at a rapid pace, perhaps no more so than direct-to-consumer personal health technology, such as smart phone enabled glucose testing, blood pressure monitoring, and activity trackers. However, there is little clarity on what obligation those commercial enterprises have to consumers. For that reason, we are concerned about the 6-year outcome of expanding the ability for individuals to safely contribute relevant and suitable electronic health information to their clinicians for engaging in shared decision making on their care and wellness goals. Specifically, we would like to see the strategies modified to include regulatory oversight—such as by the FDA—to guide the private development of health IT used directly by consumers to ensure that the data is secure, and consumers' right to privacy is not eviscerated by click-through agreements or lack of HIPAA applicability. Finally, we suggest ONC clarify in its final draft what it means by "relevant and usable" electronic health information, in its first 6-year objective. Consumers' and providers' perspectives will differ on what health information is "relevant and usable".

Goal 5: Advance Research, Scientific Knowledge, and Innovation

Objective 5B: Accelerate the development and commercialization of innovative technologies and solutions

We commend ONC for recognizing the beneficial role of individual/patient-generated health information from sensors, devices, apps, and other technologies, as well as the statement that "Individuals should have control over the kinds of data collected about them and a full understanding of how those data may be used". However, it is troubling that the objective encourages the commercialization of such technologies and solutions. Although the *quantified self*[9] market will surely evolve as part of the commercial sector, ONC should not support health IT solutions that depend on sensors, devices, and apps, solely because they are driven by market demand and supply, but also by how they can be used to further individual and public health while protecting consumers' privacy and data security. Ultimately, whether a consumer's data may be collected and used *in any way* must be constrained by that consumer's preferences on how their data is shared and protected; we therefore support the strategy of promoting transparency in communication about what information these devices are collecting and how it is being used, shared, or retained. Again, we urge ONC to ensure that this communication is presented to consumers in a way they are likely to view and understood.

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[9] *Quantified Self* is a term commonly used to refer to the movement to use technology—such as FitBit and Moodpanda—to collect data on aspects of a person's daily life in terms of inputs (such as food consumption, quality of surrounding air), states (such as mood, blood oxygen levels), and performance (physical and mental).

Objective 5C: Invest, disseminate, and translate research on how health IT can improve health and care delivery

This objective notes that “people of all abilities” should be able to benefit from health IT but none of the strategies focus specifically on identifying the barriers and solutions for those individuals who face challenges in the adoption and use of health IT, including but not limited to older adults, individuals with lower health and technology literacy, individuals with limited English proficiency, and individuals with physical and cognitive disabilities. Such a strategy should be included in the final draft.

Sincerely,

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Health Information Technology – Consumer Principles

March 2006

An interoperable system of electronic health information holds many potential benefits for consumers, including: better coordination of health care regardless of patient location, higher quality and more efficient care, increased system transparency, and patient access to information about providers that allows them to make better decisions. At the same time, such a system raises serious concerns among consumers about personal privacy, data security, and the potential misuse of their information. And while an interoperable system of electronic health information holds great promise, the many possible benefits will not be realized unless appropriate policy measures are established up front.

Consumer protections and potential benefits from health information technology (HIT) should not be left to chance. The success of efforts to promote widespread adoption of HIT, including electronic connectivity and data exchange across health care institutions, ultimately will depend on the willingness of consumers to accept the technology. Given the pervasive concerns expressed by the public about unauthorized disclosure and use of their health information, it is critical to build a foundation of public trust. To that end, as efforts move forward to develop networks for the electronic exchange of information between institutions, there must be a clear, deliberate, and open forum for addressing and setting matters of policy. As organizations representing a broad and diverse set of consumer interests, we believe that the following set of principles should underpin such efforts.

Principles

Individuals should be able to access their personally identifiable health information conveniently and affordably.

- Individuals should have a means of direct, secure access to their electronic health information that does not require physician or institutional mediation.
- Individuals should have access to all electronic records pertaining to themselves (except in cases of danger to the patient or another person).
- Individuals should be able to supplement, request correction of, and share their personally identifiable health information without unreasonable fees or burdensome processes.

Individuals should know how their personally identifiable health information may be used and who has access to it.

- Individuals should receive easily understood information identifying the types of entities with access to their personal health information and all the ways it may be used or shared. The explanation should include any sharing for purposes other than the immediate care of the individual, and should explicitly identify intentions for data use such as public health protection, quality improvement, prevention of medical errors, medical research or commercial purposes.

- Access to personal health information must be limited to authorized individuals or entities.
- Tracking and audit trail systems should be in place that permit individuals to review which entities have entered, accessed, modified and/or transmitted any of their personally identifiable health information.

Individuals should have control over whether and how their personally identifiable health information is shared.

- Individuals should be able to opt out of having their personally identifiable health information – in whole or in part – shared across an electronic health information network.
- Individuals should be able to limit the extent to which their health information (with or without personal identifiers) is made available for commercial purposes.
- Individuals should be able to designate someone else, such as a family member, caregiver or legal guardian, to have access to and exercise control over how records are shared, and also should be able to rescind this designation.

Systems for electronic health data exchange must protect the integrity, security, privacy and confidentiality of an individual's information.

- Personally identifiable health information should be protected by reasonable safeguards against such risks as loss or unauthorized access, destruction, use, modification, or disclosure of data. These safeguards must be developed at the front end and must follow the information as it is accessed or transferred.
- Individuals should be notified in a timely manner if their personally identifiable health information is subject to a security breach or privacy violation.
- Meaningful legal and financial remedies should exist to address any security breaches or privacy violations.
- Federal privacy standards that restrict the use and disclosure of personally identifiable health information should apply to all entities engaged in health information exchanges.

The governance and administration of electronic health information networks should be transparent, and publicly accountable.

- Independent bodies, accountable to the public, should oversee electronic health information sharing.
- Consumers should have equal footing with other stakeholders.

Recognizing the potential of electronic patient data to support quality measurement, provider and institutional performance assessment, relative effectiveness and outcomes research, prescription drug monitoring, patient safety, public health, informed decisionmaking by patients and other public interest objectives, systems should be designed to fully leverage that potential, while protecting patient privacy.

Implementation of any regional or national electronic health information network should be accompanied by a significant consumer education program so that people understand how the network will operate, what information will and will not be available on the *network, the value of the network, its privacy and security protections, how to participate in it, and the rights, benefits and remedies afforded to them. These efforts should include outreach to those without health insurance coverage.*

AARP
AFL-CIO
American Federation of State, County and Municipal Employees
American Federation of Teachers
Center for Medical Consumers
Communications Workers of America
Consumers Union
Department for Professional Employees, AFL-CIO
Childbirth Connection
Health Care for All
Health Privacy Project
International Association of Machinists and Aerospace Workers
International Union, United Auto Workers
March of Dimes
National Coalition for Cancer Survivorship
National Consumers League
National Partnership for Women & Families
Service Employees International Union
Title II Community AIDS National Network
United Steelworkers International Union (USW)

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