HEALTH TECHNOLOGY ASSESSMENT IN THE U.S. **A VISION FOR THE FUTURE**

A WHITE PAPER FROM THE USC SCHAEFFER CENTER — ASPEN INSTITUTE ADVISORY PANEL ON HEALTH TECHNOLOGY ASSESSMENT IN THE U.S.

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The USC Schaeffer Center for Health Policy & Economics and the Aspen Institute have together established an advisory panel to consider how the U.S. can better link the price of health technologies to the benefits they provide to patients while ensuring a sustainable healthcare ecosystem that supports innovation. While the U.S. can learn from other countries' implementation of health technology assessment, the panel's aim is to make practical recommendations that are tailored to the unique U.S. healthcare system and can garner broad support.

Authors of this white paper are a subset of the full panel. A complete panelist list, including affiliations and disclosures, can be found on page 17.

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EXECUTIVE SUMMARY

Health technology assessment (HTA) can help achieve the dual health policy goals of ensuring affordability and encouraging innovation. It represents a formal, systematic and transparent multidisciplinary process that uses explicit methods and available evidence to determine the value of a health technology.[1] The dimensions of value most often include clinical effectiveness, safety, costs and economic implications and may include ethical, social, cultural and legal issues, organizational and environmental aspects, as well as wider implications for the patient, relatives, caregivers and population.[1] The overall value may vary depending on the perspective taken, the stakeholders involved and the decision context.

HEALTH TECHNOLOGY

A health technology is an intervention developed to prevent, diagnose, or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system.[1]

The U.S. relies mostly on privately funded HTA. However, there is an economic and healthcare rationale to supplement private HTA activities by shifting some funding from the private to the public sector, and to reduce the inefficient and duplicative multiple efforts within the current HTA ecosystem. We developed a set of six recommendations for public funding of an advisory-only HTA in the U.S. that—when taken together—will bolster the HTA landscape and improve decision-making in the healthcare marketplace. The recommendations are both coherent and complementary; as such, they are meant to be taken together. On their own, individual recommendations should not be interpreted as discrete options that could provide incremental improvement.

RECOMMENDATION 1: Private HTA efforts should be encouraged.

Given the case for a potentially expanded role for HTA in the U.S., and the unique features of the U.S. market and diversity of stakeholders, we support continued HTA provision by a broad network of independent organizations that produce HTAs or engage in activities such as data collection to support HTA.

RECOMMENDATION 2: The U.S. should establish a publicly funded HTA coordinating entity, the Institute for Health Technology Assessment (IHTA), to support HTA beyond individual private efforts and to evaluate the quality of HTAs conducted by such organizations.

IHTA would (a) conduct HTA, especially for health interventions that are poorly studied in the existing literature; (b) evaluate existing HTA evidence where it exists and identify gaps where it does not; (c) engage in data collection and management; (d) advance HTA research methods and fund methodological research. Nonetheless, we affirm the need for continued HTA activities by third-party organizations even if a publicly funded HTA body is created, and recommend that the IHTA build partnerships with appropriate organizations to coordinate activities and reduce duplicative efforts.

RECOMMENDATION 3: IHTA-conducted and -approved reports should include an economic evaluation with findings presented in a disaggregated format.

While our recommendations remain otherwise neutral on methodological issues, we do recommend that economic evaluation be included in all IHTA-supported work, provided that its findings are presented in a disaggregated format.[2] Using this approach, HTA reports would include a presentation of clinical results, followed by an economic evaluation that lists all relevant costs and outcomes (consequences) associated with a healthcare intervention, stratified by relevant subgroups (e.g., age, sex, race, geography) when possible. Outcomes could include summary measures like life-years or quality-adjusted life-years but would not be limited to them, and the magnitude of health impact given the additional costs of covering a technology (i.e., opportunity costs) should be estimated for individual plans and states.

RECOMMENDATION 4: HTA should be conducted across a broad array of technologies and healthcare services—new and old—including drugs, devices, diagnostics, procedures and public health interventions.

Although HTA has tended to focus on drugs, and in particular newly approved drugs, the U.S. can benefit from HTA in all areas of healthcare. Consequently, the panel recommends that HTA be applied broadly, extending beyond drugs to include devices, diagnostics, procedures and public health interventions.

RECOMMENDATION 5: A stakeholder engagement process should provide input to the priorities and activities of the IHTA.

To ensure that the IHTA avoids the perception of bias or political influence from any one stakeholder group, we recommend that a broad group of stakeholders be involved in the activities of the IHTA to ensure it meets the needs of the U.S. healthcare system. Relevant stakeholders would belong to five broad groups including: (a) patient and healthcare consumer organizations; (b) healthcare providers (including hospitals and health systems); (c) payers (private and public); (d) employers; and (e) the drug, device and diagnostic industry.[3]

RECOMMENDATION 6: The U.S. should implement policies that allow an advisory-only HTA organization to have an impact on decision-making.

Since HTA reports would be advisory-only at the outset, we do not recommend that the Centers for Medicare & Medicaid Services (CMS) be required to make HTA-based coverage decisions. However, we do recommend that CMS be required, as part of the public comment process, both to confirm its consideration of the findings of a relevant IHTA report and to explain the impact (if any) of such findings in its coverage determinations for Medicare Part A and Part B.

INTRODUCTION

Public outcry and momentum to "do something" about healthcare spending in the U.S. have been increasing over decades, yet viable policy solutions face the challenge of reaching two related although sometimes potentially conflicting goals—ensuring affordability and encouraging innovation. Health technology assessment (HTA) can help achieve both. It represents a formal, systematic and transparent multidisciplinary process that uses explicit methods and available evidence to determine the value of a health technology.[i,1] The dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives.[1] These dimensions most often include clinical effectiveness, safety, costs and economic implications, and may—depending on the technology—include ethical, social, cultural and legal issues, organizational and environmental aspects, as well as wider implications for the patient, relatives, caregivers and population.[1] The overall "value" may vary depending on the perspective taken, the stakeholders involved and the decision context.

HTA, when conducted most effectively, provides a valuable input for public and private decision-makers who must allocate limited resources across a wide array of health interventions. Yet, over the last couple of decades, some have eschewed the explicit use and funding of HTA in the U.S. as a possible means to provide insurers, clinicians and patients with evidence to make more informed healthcare decisions. In part, this is due to concern about lack of data, methodological limitations, insufficient attention to equity and improper inference, but researchers have addressed many of these issues.[4-10] It also reflects dynamics observed in pluralistic health systems such as that of the U.S.—highlighting traditions of individualism, localized and market-based decision-making, and a drive to advance medical progress. Thus, the expansion of HTA must ensure it delivers to all interested parties.

The U.S. was not always averse to publicly funding HTA. The federal government was a pioneer in technology assessment in the 1970s and 1980s through the Congressional Office of Technology Assessment (OTA).[11] Subsequent to the OTA's defunding in 1995—for mainly political reasons[12]—the U.S. has lacked a coordinated federal HTA process. Despite calls for a national HTA agency,[11, 13] the U.S. HTA landscape has featured mostly nongovernmental actors—multiple organizations that independently undertake HTA activities, including universities (some of which collaborate through the Drug Effectiveness Review Project), nonprofits such as the Institute for Clinical and Economic Review (ICER), individual private payers, as well as a select few government agencies including the Department of Veterans Affairs and the Agency for Healthcare Research and Quality (AHRQ).

The lack of U.S. government involvement in HTA is rooted in concerns about rationing and equity.[14-16] When the Patient-Centered Outcomes Research Institute (PCORI; established in 2010) was initially conceived as a new comparative effectiveness organization, it was barred from considering analyses or recommendations based on cost-effectiveness thresholds, in part due to concern about the potential for discrimination against older or disabled individuals.[17-19] Consequently, PCORI cannot provide guidance that aggregates data on clinical benefits and costs to obtain a complete picture of the value of different technologies.[20] But that does not mean there is no demand for HTA in the U.S. Recent policy proposals that would implicitly use the HTAs conducted in other countries to determine U.S. drug prices signal that some policymakers value such information.[21-23]

The result is that the U.S. relies mostly on privately funded HTA, with a number of consequences. First, HTA efforts in the U.S. are focused on technologies where some private organization has a vested financial interest. This approach generally neglects health interventions—e.g., surgeries, processes of care, public health interventions or clinical decision-making protocols—without patent holders.[ii] Second, it introduces the possibility of bias that might arise if either payers or suppliers were funding assessments.[iii] Private funding of HTA simultaneously leads to underprovision of HTA that encompasses broader societal interests today and for the future and overprovision of HTA findings in areas that minimally add to existing information and might only align with special interests.

Information about the value of medical care is a public good that can benefit a wide range of actors. A mix of public and private funding and broad stakeholder involvement could improve the usability of HTA information. The current structure of the U.S. healthcare system, with multiple payers individually and independently determining coverage and negotiating with providers and manufacturers,[26, 27] does not lend itself to wholesale adoption of a single, one-size-fits-all HTA process. However, due to political, regulatory, informational and behavioral barriers that prevent prices from reflecting the value of health technologies to consumers, there is an economic and healthcare rationale to supplement private HTA activities by shifting some funding from the private to the public sector, and to reduce the inefficient and duplicative multiple efforts within the current HTA ecosystem.

With this landscape in mind, the USC Schaeffer Center and the Aspen Institute partnered to create an advisory panel to develop policy recommendations to guide the future of HTA in the U.S. Chaired by three leading experts—Darius Lakdawalla, Peter Neumann and Gail Wilensky—the panel recruited 16 experts from academia, patient advocacy, government and industry, including three international experts. The panel focused on the portion of HTA that identifies, synthesizes and presents evidence on effectiveness and cost-effectiveness, an important first step in moving the HTA landscape forward in the U.S. The panel did not consider in depth how HTA should be used by decision-makers in deliberative processes (sometimes referred to as appraisal or contextualization),[5] because that step includes political and ideological judgments. The advisory panel's recommendations were developed through discussions at three full-panel meetings in 2019 and 2020, and incorporated feedback and targeted input from additional small-group discussions and panelist surveys and comments.

The panel's discussions and recommendations for HTA in the U.S. outlined market complexities in healthcare and features of the U.S. healthcare system that could be mitigated by more comprehensive, objective and independent HTA studies. The balance between affordability and innovation—defined as the development and delivery of new or improved health technologies, products or systems[28]—is particularly important in the debate over healthcare spending in the U.S. context. Importantly, as we consider a public-sector role for funding HTA in the U.S., the process should be designed to ensure that assessments produce high-quality outputs that are not driven by a particular stakeholder agenda, but

i A health technology is an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program or system.[1]

ii The exclusion of non-drug technologies from assessments is partly driven by data and methodological limitations.[24, 25]

iii While publicly funded HTA could potentially reveal government bias, this outcome would be minimized if the organization that conducts the HTA is fully independent from the organization that uses the HTA to make decisions.

rather are useful for diverse payers and geographies. It must further account for the heterogeneity of the U.S. population, which affects disease prevalence, healthcare preferences and priorities, as well as political considerations. Furthermore, public funding should promote the development of HTA evidence by a wide variety of private organizations.

The remainder of this paper frames the advisory panel's recommendations for public funding of HTA in the U.S. First, we present the economic rationale for HTA-based information about value and for funding its production publicly rather than primarily relying on private funding. Then, we outline the panel's recommendations for public funding designed to ensure a more comprehensive and objective base of HTA evidence in the U.S.

THE ECONOMIC RATIONALE FOR PUBLICLY FUNDED HTA IN THE U.S.

When suppliers sell directly to consumers, and when consumers bear the full cost and have good information about value, alignment between prices of technology and the value created for consumers is more likely to occur. For example, there is no need for a formal technology assessment in the market for smartphones because consumers have direct access to good, relevant and meaningful information, allowing them to make those assessments for themselves. However, the market for medical technology involves a great deal of intermediation. Treatment and clinical decision-making is complex, and patients often lack medical literacy to differentiate between benefits and risks associated with alternative care pathways, necessitating reliance on provider knowledge. In addition, third-party payment and opaque pricing practices make consumers less sensitive to prices and disrupt the signals of consumer value transmitted back to innovators.

For a host of reasons, U.S. health insurers—and in the pharmaceutical context, pharmacy benefit managers (PBMs)—do not fully consider the value perceived by consumers. For example, even for therapies with long-term benefits, many insurers focus on short-run cost rather than lifetime value because beneficiaries often switch insurers before benefits are fully realized.[iv] This misalignment persists because consumers have poor information about value and how to select between health insurance plans when options for coverage exist.[31-34] As a result, they cannot meaningfully influence insurers, employers, technology producers or government against setting prices that misrepresent value.[32] Consumer influence could be improved by providing more choice among insurers and health plans, both in terms of the number of plans as well as the benefit design across plans,[v] but consumers (and the insurers that negotiate on their behalf) would need to be well-informed about value for a dizzying number of medical technology options. Even if such information were provided, consumers may still find it difficult to make effective choices regarding a health plan's value and may often make poor decisions leading to suboptimal plan match and overpaying for insurance coverage.[32, 33]

Other market distortions cause various stakeholders in the healthcare system to make decisions not entirely driven by value or clinical benefit. In the case of drugs, volume-based reimbursements continue to dominate contracting agreements between manufacturers and PBMs/payers. Higher volumes drive volume-based rebates offered by manufacturers, which in turn drive preferred formulary placement for manufacturers offering the highest rebates. Higher co-pays and patient out-of-pocket costs might only reflect a shift in payment responsibilities from insurers to consumers, rather than additional value provided by the technology.[35, 36] This system rewards the growing divergence between list and net prices and the selection of drugs with the largest rebates.[37] Even in the case of Medicare Part D, where rebates reach beneficiaries through lower premiums,[38] the value of insurance is diluted for patients whose out-of-pocket drug costs are based on the list price. Provider behavior, particularly among those who administer Medicare Part B drugs, is also influenced by reimbursement policies that favor more expensive drugs.[39-41] Market distortions also extend to other non-drug technologies and services: Unnecessary and inefficient care, as well as missed opportunities for preventive care, have generated over $300 billion in excess costs.[42, 43] Although the Choosing Wisely initiative aimed to educate physicians and patients about the overuse of common tests, treatments and procedures, reductions in unnecessary care have been slow.[44-48]

While economists might imagine a world in which markets price medical technology "appropriately," political, regulatory, informational and behavioral barriers in the real world remain. Thus, a case can be made for HTA as a "second-best" method for aligning medical technology prices with the benefits they provide. If prices are set too low relative to value, innovators may be reluctant to invest in R&D, which stifles future innovation. On the contrary, prices set too high relative to value stimulate inefficient levels and sometimes types of innovation. HTA has been adopted overseas for reasons other than improving incentives for innovators. For example, the National Institute for Health and Care Excellence (NICE) was created as a single-point decision-maker for the entire health system in England and Wales for selected technologies to address inconsistencies in access at the local level where decisions are made.[49] The U.S. healthcare system faces different challenges than other countries in part because it lacks a national, single-payer system. Reimbursement based largely on volume rather than value and the market failures due to intermediation are among the issues that currently hinder value-driven decision-making in the U.S. and discourage use of HTA. Simply introducing a "NICE-like" entity in the U.S. would not be sufficient to ensure healthcare prices are linked to value if payers and PBMs still make volume-driven decisions and face fee-for-service providers.

Some may suggest that expanded or more coordinated HTA through public funding is not necessary in the U.S., since the private market is already generating HTA information. But HTA is fundamentally about producing information, which is a public good—that is, although many parties can benefit from the information resulting from HTA, the organization conducting HTA bears its full cost. As a result, even while HTA activities across organizations may be duplicative, certain types of HTA are undersupplied by private markets or not publicly available.[26, 50] This makes it imperative for public funding to fill the gap, thus helping to ensure that the optimal level of information is available. ICER, which some argue has filled a gap in the U.S. healthcare system,[51, 52] serves as an example of a private organization attempting to supply a public good. While ICER's methods are reasonably transparent and include stakeholder engagement, ultimately the organization and its process are accountable only to itself and its funders.[vi] Further, ICER's budget and resources are limited in comparison with more well-funded government agencies, which restrains its ability to conduct HTAs on all relevant topics. As a result, topic selection in recent years has been primarily focused on newly approved, high-impact drugs even though HTAs in other areas would be useful for healthcare decision-makers. Lack of access to proprietary data represents another practical constraint to privately supplied HTA because analyses conducted as part of HTAs are limited to publicly available evidence.[55] For example, some economic models rely on list prices because net prices are not always disclosed. A publicly funded HTA organization may be given more authority to collect proprietary data, which would reduce the number of assumptions required in modeling and improve the credibility of results.

PUBLICLY FUNDED HTA IN THE U.S.: RECOMMENDATIONS

We developed a set of six recommendations that—when taken together—will bolster the HTA landscape in the U.S. going forward. The recommendations are both coherent and complementary; as such, they are meant to be taken together. On their own, individual recommendations should not necessarily be interpreted as discrete options that could provide incremental improvement.

Most ambitiously, we recommend establishing a new publicly funded HTA organization—the Institute for Health Technology Assessment (IHTA)—to support the proliferation of HTA beyond individual private efforts and to evaluate the quality of HTAs conducted by individual organizations. Prior to outlining roles of the IHTA in Recommendation 2, we affirm the need for continued HTA activities by third-party organizations even if a publicly funded HTA body is created.

RECOMMENDATION 1: Private HTA efforts should be encouraged.

Given the case for a potentially expanded role for HTA in the U.S., and the unique features of the U.S. market and diversity of stakeholders, we support continued HTA provision by a broad network of independent organizations that produce HTAs or engage in activities such as data collection to support HTA. This network would include, but not be limited to, organizations that are currently conducting HTAs in the U.S. market.

Organizations currently conducting HTAs for the U.S. market represent a range of approaches that illustrates the need for a broad HTA network but also the gaps and inconsistencies that a more coordinated approach to HTA could resolve. For example, ICER—a private nonprofit organization with growing influence,[vii] a well-developed and reasonably transparent HTA process, and work products that are freely and publicly available—operates very differently from private payers, whose HTA processes are proprietary and therefore difficult, if not impossible, for outsiders to evaluate. More generally, individual HTAs may vary in quality or reproducibility and might not meet decision-makers' needs. Moreover, many HTAs focus on newly approved

iv Insurance turnover prior to Medicare eligibility (at age 65) is partly driven by employment changes since approximately 58% of the non-elderly population has employer-based health insurance,[29] and median employee tenure with their current employer is four years.[30]

v We note that this would be a politically challenging task and would involve decoupling health insurance from employment.

vi ICER receives 12% of its funding from health plans and provider groups, 17% from manufacturer contributions, and 70% from nonprofit organizations, including $19 million from Arnold Ventures.[53, 54]

vii In the absence of other HTA bodies in the U.S., ICER's visibility and influence has grown among private and public payers who are increasingly using ICER reports for drug coverage and reimbursement decisions.[56]

pharmaceuticals, leaving a large gap in the evidence for other biomedical technologies and healthcare services, including devices, diagnostics and procedures.[57] Finally, with numerous independent entities conducting HTAs on the same technologies, total output is currently duplicated rather than spread across more technologies where new information is needed. An organization designed to improve standardization, facilitate quality control, and increase transparency and coordination of the HTAs being supported by independent organizations would reduce duplicative effort and increase the benefit associated with the resources already being spent on HTA in the U.S.

RECOMMENDATION 2: The U.S. should establish a publicly funded HTA coordinating entity, the Institute for Health Technology Assessment (IHTA), to support HTA beyond individual private efforts and to evaluate the quality of HTAs conducted by such organizations.

We recommend establishing a publicly funded HTA entity, the IHTA, to support the appropriate use of HTAs and to evaluate the quality of HTAs conducted by individual organizations. Even with the establishment of the IHTA, private organizations that conduct HTAs would continue to provide valuable resources for decision-makers and have the flexibility to focus on particular interventions or diseases and to cater to individual stakeholders. A full organizational charter for the IHTA is beyond the scope of our recommendations, but we outline four roles for the IHTA that both complement and add value to the existing HTA ecosystem in the U.S. In addition to providing coordination, oversight and quality control for third-party studies, the IHTA would conduct its own HTAs, particularly in areas that currently lack useful and objective HTA studies. The IHTA would also be responsible for producing, distributing and warehousing HTA data, and would provide funding and training to support the development of HTA methods, particularly for non-drug technologies, and ensure a robust HTA research environment in the U.S.

IHTA Role 1: Conduct HTA, especially for health interventions that are poorly studied in the existing literature

The IHTA would have purview to evaluate any existing or new medical technology, including drugs, devices, diagnostics, procedures, public health interventions and other health services. The IHTA would be responsible for implementing a prioritization process that ensures the evaluation of a wide array of interventions. Prioritization should be based on stakeholder input or alternative processes such as those proposed by the National Academy of Medicine (NAM) that consider spending and geographic variation.[58, 59]

HTA activities conducted by third-party organizations—which might include private manufacturers and health plans, consulting firms, or nonprofit organizations such as ICER and academic research centers—would likely continue to reflect the preferences and priorities of their private funders. As a result, we expect third-party HTAs to continue to concentrate on new technologies because demand for information is higher at market introduction and during coverage and pricing negotiations. To ensure all technologies selected in a prioritization process receive assessments, the IHTA may therefore decide to focus its center-initiated HTAs on devices, diagnostics, procedures, public health programs and existing drugs that are less frequently evaluated by existing HTA organizations in the U.S.

The IHTA should build partnerships with appropriate organizations to coordinate activities based on the priority-setting process and reduce duplicative efforts. ICER provides an example of an organization that already has a well-established infrastructure and will likely decide for itself to continue focusing on newly approved drugs. AHRQ Evidence-based Practice Centers (EPCs) already conduct assessments for the Medicare population on behalf of CMS, and would provide a natural partner for the IHTA in non-drug assessments.[viii] Similarly, assessments of public health interventions such as vaccines, diagnostics or other preventive services may build on existing work and guidance provided by the Advisory Committee on Immunization Practices and the U.S. Preventive Services Task Force.

IHTA Role 2: Evaluate existing HTA evidence where it exists and identify gaps where it does not

Although the IHTA would conduct its own assessments, in many ways its work would resemble that of the Food and Drug Administration (FDA)—the assessment of the quality and completeness of data from clinical studies, including randomized clinical trials (RCTs) and real-world data, and the establishment of rules on whether and how a new product can be marketed.[ix] Under this construct, the IHTA would provide quality control for private providers of HTA reports by setting standards for data adequacy, developing and promulgating sound analytic methods, and sharing reporting templates that ensure HTA information is presented in a way that is useful to a broad range of decision-makers. The AHRQ EPC Program provides a potential model for this setup: Currently, nine organizations have been designated AHRQ EPCs, and while they work independently, EPCs follow standardized methods.

The IHTA may encourage multiple and competing HTAs for each technology of interest because final reports will vary based on inclusion and evaluation of evidence. All HTA analyses submitted to the IHTA for consideration should ideally provide all source code for validation or replication by other researchers, but at a minimum be thoroughly documented. The IHTA would rate the quality of each HTA, including a critique of assumptions and included/excluded evidence, noting when the approved standards and methods are used or not, so that decision-makers can understand the reliability of each HTA—creating, in effect, a "Good Housekeeping HTA Seal of Approval."

The IHTA would compare submitted HTA studies and guide decision-makers on the most reliable information, data and economic models. The IHTA would also review uncertainties in the HTA evidence and make recommendations for additional data collection or studies required to resolve them.[61] The IHTA would make recommendations on which HTAs would benefit from updates once new data become available, but third-party organizations would be encouraged to update HTAs more generally, and to revise recommendations as the data evolve. In addition, the IHTA would identify underserved areas of the literature, particularly related to medical interventions that are not patentable, such as medical procedures, healthcare delivery methods and off-patent technologies. Below, we discuss how these gaps in the literature could best be addressed.

Because we do not recommend that the IHTA be granted regulatory authority, there may be concern that private organizations that conduct HTAs may be unwilling to engage with the IHTA or submit reports, data or methods. Under such a circumstance, the ability of the IHTA to partner with external organizations and build on existing HTA capabilities in the U.S. would be diminished, potentially resulting in the need for additional resources for the IHTA to conduct internal HTAs. However, our recommendation that CMS be required to consider (but not required to use) IHTA reports in its Medicare coverage decisions (see Recommendation 6), along with the enhanced value provided by the "Good Housekeeping HTA Seal of Approval" should incentivize private organizations to engage with the IHTA.

IHTA Role 3: Engage in data collection and management

Along with setting standards for data adequacy and evaluation methods, the IHTA would also facilitate primary data collection, including the development of data-collection infrastructure, to aid future analyses, and would develop partnerships with existing organizations such as the Centers for Disease Control and Prevention (CDC), AHRQ, the National Institutes of Health (NIH) and PCORI. At a minimum, the IHTA could facilitate data collection to improve subgroup analyses and include information about disease epidemiology (incidence, prevalence, comorbidity) stratified by age, sex, income group, race, ethnicity and geography. Another important gap the IHTA could address is the expansion of data-collection processes to measure additional outcomes, such as disease severity, workplace productivity and caregiver burden, for incorporation in future studies.

In recent years, the FDA has increased the number of products approved for the market under fast-track approval processes.[62] As a result, these products tend to have a smaller evidence base available at launch[63] and their clinical and economic implications are more uncertain. The IHTA could help implement systematic data collection to support post-launch evidence and coverage with evidence development, and novel payment arrangements such as outcomes-based agreements.[64] Post-launch data collection could also help quantify variability in treatment response, which plays a role in how patients value treatment.[9] These additional data could in turn inform approaches to modeling uncertainty in future HTAs. Clinical and economic analyses could be updated as additional real-world data become available. These data could foster subgroup analyses that are more relevant for certain payers, or simply focus on longer-run outcomes that are unavailable as part of RCTs and other studies used to support FDA approval.

Insufficient or low-quality data represent a significant hurdle for conducting HTA for non-drug technologies. The IHTA could help fill this gap by providing funding for and facilitating data collection in areas where it is needed. Partnerships with provider organizations, patient groups and hospitals could be developed to collect data on services and procedures, with the potential benefit of standardizing such data reporting across hospitals.

viii Recent assessments have considered wound treatments, cardiac resynchronization therapy and bariatric surgery.[60]

ix Unlike the FDA, the IHTA would not be a regulatory body.

All collected data would be managed by the IHTA and available[x] for subsequent analysis by any organizations that submit analyses to the IHTA for its "Good Housekeeping HTA Seal of Approval." Successful private sector examples could be used as a model for this functionality, including the National Opinion Research Center[65] and the Health Care Cost Institute.[66]

IHTA Role 4: Advance HTA research methods and fund methodological research

Researchers continue to explore ways to improve existing HTA methods, including economic analysis.[5,67-69] For example, health technologies may provide additional benefits to patients that are not currently captured by quality-adjusted life-years (QALYs), such as equity considerations, the value of hope or reduced fear of contagion.[70-74] Identifying and quantifying these benefits represents a first step, since researchers will need to decide whether and, if so, how to correctly incorporate them into HTAs, whether through stakeholder discussions and contextualization or explicit methods such as multiple-criteria decision analyses.[75, 76] Recent work has proposed methods to generalize QALYs to incorporate additional features of consumer preference.[9, 74] In addition to quantifying benefits, empirical estimates of opportunity costs—in terms of health outcomes and thresholds for decision-making—have begun to emerge as more costly technologies are funded, including in the U.S.[77] However, these elements have yet to find their place in health economics, and more discussion will be needed to understand the consequences of incorporating them into traditional analyses and their role in decision-making.

The IHTA could help foster these discussions and, accordingly, should conduct research internally and fund external studies that address other methodological gaps. Funding for external studies should be targeted at research in underserved areas of the literature such as medical procedures, diagnostics, healthcare delivery methods, generic drugs and public health interventions. Although work has been done by NAM to develop methods related to priority setting in HTA, this would be an important research area for the IHTA to consider.[58] Partnerships with PCORI, which has focused on funding patient-centered research, could help advance incorporating patient aspects into HTA.

IHTA financing

The ultimate funding level for the IHTA would depend on the final scope of the organization. As a basis of comparison, AHRQ operates with a budget of $340 million per year (roughly $1/citizen); PCORI received $615 million in revenue for fiscal year 2019 ($120 million in federal appropriation,[xi] $345 million in fees from insurers, $116 million in transfers from Medicare Trust funds and $34 million in interest income) and had $390 million in expenses; and the FDA has a $5.7 billion per year operating cost, with just under $3 billion per year funding the areas relevant for the IHTA (human drugs, biologics and medical devices).

While numerous funding mechanisms are available, both the FDA and PCORI models place some financing responsibilities on those organizations that stand to benefit most from their activities: the pharmaceutical and health insurance industries.[xii] Similarly, HTA organizations in other countries, including NICE (in the UK) and the Canadian Agency for Drugs and Technologies in Health, augment government funding with industry fees.[75, 79] In the case of IHTA, insurers, manufacturers and providers, including hospitals, would benefit from its activities and therefore should contribute. Presumably, this model might be cost neutral or cost saving for stakeholders if the IHTA's activities allow them to reduce duplicative internal HTA efforts.

IHTA organization and governance

Success hinges on two features. First, the IHTA must not be perceived as having bias in favor of any one stakeholder (payers, manufacturers, providers, patients or otherwise). As such, IHTA governance and management should be independent of healthcare payers (public or private), manufacturers, and providers of medical technologies or services. This would exclude housing the IHTA within the Department of Health and Human Services and its subsidiary organizations, including CMS, AHRQ, CDC, NIH and FDA.[xiii] Similarly, the IHTA should not be incorporated within organizations in any way related to healthcare financing (e.g., insurance organizations) or production (e.g., professional organizations of health providers, universities with medical center affiliations).

x De-identified to be compliant with HIPAA rules.

xi PCORI receives funding through mandatory annual appropriations (totaling approximately $3 trillion over 10 years), which were legislated as part of PCORI's reauthorization.[78]

xii The FDA collects user fees from pharmaceutical companies to support the drug-approval process and PCORI receives fees from insurers. Presumably, private insurers pass along minimal extra cost as added insurance premium costs, with negligible effects on disenrollment.[78]

xiii Direct affiliation (whether through shared management or organizational structure) should be distinguished from stakeholder engagement in the IHTA, which we outline in Recommendation 5.

Second, the IHTA must be independent of political influence and pressure—from either government or any stakeholder group. For example, by the end of its tenure, the OTA was perceived by some policymakers and stakeholders as operating in a partisan way, which contributed to the efforts in Congress to end its funding and eventually dissolve the agency, while others argue that it was a partisan reaction to the OTA's conclusions on certain topics that hastened its demise. Independence precludes a membership-based structure (e.g., National Quality Forum) since that would require reliance on membership fees provided by a subset of HTA stakeholders, which are likely to create biases in membership that could influence or lead to the appearance of influence in the IHTA's work. Finally, its funding must be assured and not subject to the political whims of the federal appropriations process. While this will be impossible to achieve wholly, at a minimum the IHTA's funding must be secured in the long term to ensure independence.

Several organizations offer precedents for the organizational and governance structure for the IHTA. The Government Accountability Office (GAO), Congressional Budget Office (CBO), and The Medicare Payment Advisory Commission (MedPAC) provide examples of organizations that report directly to Congress. Alternatively, the IHTA could be a freestanding, quasi-public organization: PCORI serves as a useful model for this approach. We recommend several additional features for a successful IHTA:

- Separate 501(c) corporation (if the organization is freestanding)
- Expert advisory panels, which incorporate patient viewpoints
- Methodological committee central to its operation
- Mandatory peer review for primary research
- Board of governors and perhaps a broader advisory stakeholder forum
- Five-year performance review cycle
- Strict conflict-of-interest disclosure rules

Ultimately, the final organizational and governance structure for the IHTA would be one that is least subject to political pressure from major interest groups (innovators, providers and payers) and most inoculated from shifts in the political majority.

RECOMMENDATION 3: IHTA-conducted and approved reports should include an economic evaluation with findings presented in a disaggregated format.

HTA takes many forms, and although there are valuable lessons to be learned from HTA implementation in other countries, there is no one correct way to implement an HTA process. HTA often begins with a question or problem statement (e.g., "What is the value of intervention Y for disease X in population Z?" where the value is represented by the intervention's clinical outcomes in relation to its costs) and the subsequent evidence synthesis and analysis encompasses clinical evidence (safety and efficacy), cost and economic evaluation, and ethical, social and legal impacts. Cost-effectiveness analysis (CEA)—commonly used for economic evaluation—including the use of QALYs, has been a contentious issue in the U.S. As a result, currently Medicare cannot use CEA in coverage decisions for treatments and diagnostics, and the Affordable Care Act (ACA) barred PCORI from using a dollars-per-QALY measure as a threshold to establish recommendations.[80-83]

Given political resistance to CEA and the dollar-per-QALY measure in the U.S., some may suggest that the IHTA should focus its work solely on clinical evaluation. But this would leave the economic evaluation—which provides critical information required for decision-makers to align prices with value and develop appropriate guidelines and clinical pathways—to privately funded for-profit and nonprofit entities. Prior expert panels have recommended economic evaluation take the form of CEA, which relies on the QALY as a measure of benefit.[4, 84] However, economic evaluation can take many forms, and any economic evaluation that involves aggregating costs and clinical benefits into a single metric would necessarily involve normative judgments.[85]

While our panel is agnostic about which methods to use in economic evaluation in the U.S., we do recommend that economic evaluation be included in all IHTA-supported work, but that the findings be presented in a disaggregated format.[2] Using this approach, HTA reports would include a presentation of clinical results, followed by an economic evaluation that lists all relevant costs and outcomes (consequences) associated with a healthcare intervention, stratified by relevant subgroups (e.g., age, sex, race, geography) when possible. Outcomes could include summary measures such as life-years or QALYs but would not be limited to them, and the magnitude of health impact given the additional costs of covering a technology (i.e., opportunity costs) should be estimated for individual plans and states. Presenting economic evaluation in a disaggregated manner leaves the normative aspect of economic evaluation to the decision-maker rather than the organization producing the information. This approach provides flexibility in reporting and allows room to modify reports as new methods or outcome measures are validated.

This recommendation reflects the political atmosphere as well as legal barriers in the ACA that prevent the use of dollars-per-QALY or any similar measure that "discounts the value of life because of an individual's disability."[19, 75] While QALYs are controversial, they incorporate both life extensions

and quality improvements incurred by health interventions and are well-understood. Moreover, recent methodological developments have suggested alternative value judgments that may address the perceived bias in the value of life extension or quality-of-life improvements for people with disabilities because of the lower quality of life they experience.[9, 10] Nevertheless, inclusion of these measures in HTA reports would require legislative changes.

Although legislative feasibility provided one aspect for consideration for this recommendation, our support for disaggregated reporting acknowledges that the complexity of the decentralized and market-based U.S. healthcare system cannot be adequately captured by a single measure or threshold. Importantly, a disaggregated presentation may discourage hyper-focus (by media or decision-makers) on the incremental cost-effectiveness ratio or arbitrary cost-effectiveness thresholds and encourage a more nuanced and useful discussion about all costs (including opportunity costs), clinical benefits and perceptions of value.[xiv] Finally, HTA reports that present all costs and outcomes in a disaggregated manner may be more useful for all payers and stakeholders, who can evaluate information on value as it applies locally to their population and disregard irrelevant components.

RECOMMENDATION 4: HTA should be conducted across a broad array of technologies and healthcare services—new and old—including drugs, devices, diagnostics, procedures and public health interventions.

Although HTA has tended to focus on drugs, and in particular newly approved drugs, the U.S. can benefit from HTA in all areas of healthcare. Consequently, the panel recommends that HTA be applied broadly, extending beyond drugs to include devices, diagnostics, procedures and public health interventions. Broad application of HTA would mirror the activities of the OTA, whose assessments considered a wide range of topics, including cholesterol screening, computed tomography scanners, HIV vaccines and genetic testing.[86] Drugs generally receive greater attention from privately funded organizations[87, 88] in part because they have more readily available data, making them easier to evaluate using established HTA methods. Moreover, their government-protected patents and exclusivity make them natural targets of assessment processes. But drugs comprise only approximately 15% to 20% of healthcare spending in the U.S.;[89-91] excluding non-drug technologies from HTA ignores most sources of healthcare spending and areas where prices might not reflect value.[24, 25, 43]

HTAs should also span both existing and new technologies to provide information to decision-makers who may consider whether resources should shift following the introduction of innovations. Deciding among competing health technologies presents a challenge, but decisions grounded in the scientific evidence provided by HTA reduce the degree of subjectivity or perception of political bias. In addition, as the U.S. strives to improve healthcare quality while managing rising health spending, success will depend in part on eliminating low-value, wasteful care.[92-94] In particular, technologies or interventions that increase healthcare costs but do not improve health benefits ("no-value care") should be identified and phased out.[57] While many no-value care interventions have been identified by professional medical societies, HTA has not yet been widely used to identify treatments that increase costs but fail to improve health outcomes across the full spectrum of care.[95] Given the large number and types of technologies under consideration for coverage by decision-makers, a publicly funded HTA organization would be well-positioned to help prioritize and select which technologies would undergo HTA.

RECOMMENDATION 5: A stakeholder engagement process should provide input to the priorities and activities of the IHTA.

To ensure that the IHTA avoids the perception of bias or political influence from any one stakeholder group, we recommend that a broad group of stakeholders be involved in the activities of the IHTA to ensure it meets the needs of the U.S. healthcare system. Relevant stakeholders would belong to five broad groups including: (a) patient and healthcare consumer organizations; (b) healthcare providers (including hospitals and health systems); (c) payers (private and public); (d) employers; and (e) the drug, device and diagnostic industry.[3] We note that payers are a unique group since they are both a stakeholder in the HTA process and a decision-maker. Stakeholder representation should be balanced across the five groups and by geography (e.g., state or region). Beyond stakeholder categories, others with expertise in HTA methods or relevant healthcare fields should participate in the IHTA's activities, including academics or experts in health economics, health disparities, epidemiology, or health services and health policy research, as well as representatives from government agencies that might interface with an HTA organization such as the FDA or NIH.[xv] All participants should be subject to conflict-of-interest disclosures, and non-stakeholders (such as academics or government representatives) must not represent any stakeholder's views.

The IHTA's stakeholder engagement process must be sufficiently insulated from lobbying and political interests, and all stakeholders must agree and be held accountable to the operating principle that expanding HTA capacity includes explicit but disaggregated consideration of outcomes and cost as part of HTA reports in the U.S. Furthermore, all stakeholders should agree to the goal of promoting rapid uptake of high-value technologies, both in the U.S. and internationally. Given the contrasting and potentially competing interests of stakeholders, this process will face steep hurdles and has the potential to limit the impact of the IHTA's work. To counter this possibility, we recommend clear rules for stakeholder engagement be laid out as part of the IHTA's charter. Although the IHTA may initially focus on HTA production and evaluation as described in Role 1, the charter should include timelines under which the IHTA will expand its directive to include moderating multi-stakeholder deliberations. These deliberations would inform recommendations for inclusion in HTA reports, help reconcile competing stakeholder viewpoints and encourage report uptake by decision-makers.

Stakeholder involvement would ensure representation of interests in and legitimacy of HTA, which in turn would enhance the prospects of HTAs playing an impactful role in policy making.[96] A stakeholder engagement process would also help safeguard the long-run independence, objectivity and relevance of the IHTA.[11] Furthermore, a reasonable, fair and transparent stakeholder engagement process both in creating the IHTA and the conduct of its activities should aid in achieving political and public acceptance of HTA as a healthcare decision aid.

RECOMMENDATION 6: The U.S. should implement policies that allow an advisory-only HTA organization to have impact on decision-making.

Our proposals have concentrated on an HTA organization that focuses on developing a scientifically rigorous evidence base to support decision-making in the U.S. though we recognize that these decisions can have global implications on access to medicines, for example. However, we make no recommendations for how HTA should be used by decision-makers. Instead, we envision the reports and recommendations developed by the IHTA as advisory in nature to provide decision-makers, in the U.S. and worldwide, with information to use as they deem appropriate. Moreover, we identify and articulate a role for Medicare as a proving ground for the advisory use of HTA evidence.

As a first step to increase the impact of an advisory-only IHTA, educating the users of HTA, medical practitioners and the general public on the merits of HTA would improve the chances that HTA reports and recommendations will be understood and appreciated as more than a rationing mechanism.[xvi]

While we do not make specific recommendations about how HTAs reviewed or produced by the IHTA should be used by decision-makers, we believe reasonable steps could be taken by the IHTA to support and encourage their use. Payers already use HTA information in coverage decisions (usually in an opaque manner), although the focus may skew toward cost-effectiveness thresholds rather than the full scope provided by disaggregated HTA reports that the IHTA would produce.[98] Many payers make their coverage criteria publicly available, and sometimes provide explicit rationale for their decisions.[26, 50] However, payer accountability to their enrollees would increase if payers provide transparent reports describing what HTA information they use in decision-making, including detailed rationale to support coverage decisions. Even if health plans or insurers use HTA information differently, it could make consumers better off if they have the ability to switch to a plan that uses HTA in a way that reflects their preferences.

The use of HTA may also aid the removal of other market drivers, and switch the incentive back to what is best for the patient rather than most efficient contractually. To encourage consideration of HTA more generally, the U.S. will need to address current market incentives that favor volume- or rebate-driven decisions. Without additional encouragement for value-based pricing, it may be difficult for high-quality HTA information to inform price negotiations and formulary decisions. The flow of high-quality HTA information provided by or facilitated by the IHTA would be preferable to volume-based or rebate-based pricing in driving decisions related to formulary placement, adoption of biosimilars and generics, and determining patient out-

xiv We note that while ICER produces many results in their reports, the media attention tends to focus on the incremental cost-effectiveness ratio or value-based price, which belies the degree of discourse ICER undertakes in its assessments.

xv We noted earlier that, in order to succeed, a stakeholder engagement process should be sufficiently insulated from political interests. Therefore, the inclusion of government-agency representatives in such a process presents the risk of political interference; to avoid potential conflict, government-agency representatives would be invited to participate in a non-voting capacity.

xvi The role of information in consumers' healthcare decisions should not be underestimated. For example, studies have found higher enrollment rates in ACA exchanges in markets with more federally sponsored advertising and lower enrollment in markets where ads opposed the ACA.[97]

of-pocket costs. Further, a shift from volume-based to value-based reimbursement agreements,[99] which CMS has encouraged,[100] creates a better environment for the viewpoints of all stakeholders to be reflected in value.

Since HTA reports would be advisory-only at the outset, we do not recommend that CMS be required to make HTA-based coverage decisions. However, we do recommend that CMS be required, as part of the public comment process, both to confirm its consideration of the findings of a relevant IHTA report and to explain the impact of such findings in its coverage determinations for Medicare Part A and Part B. In addition, CMS should have the ability to commission IHTA reports as another piece of information in coverage decision analysis. CMS already uses an evidence-based process in its coverage decisions, which sometimes includes an external technology assessment; using additional elements of HTA such as cost in its decision-making is a logical and reasonable extension.[101] CMS could pilot reports describing whether and how HTA was used, as well as its rationale for coverage decisions. These pilots would also help determine data and reporting gaps in HTA reports so that organizations that produce HTAs (including the IHTA) could modify their outputs appropriately. Because state Medicaid programs have varying needs and requirements, this recommendation applies only to Medicare coverage determinations.

CONCLUSION

One of the highest concerns of the U.S. public is rising medical care costs.[102] Currently, several public payers are required to exclude cost considerations in their decision-making—but how long will this be sustainable? While piecemeal HTAs conducted by individual organizations in the U.S. provide a foundation for developing the necessary evidence base to support the decisions that influence healthcare spending, they have struggled to produce a practical impact (ICER being a notable exception in recent years). Moreover, improvements in and consensus around the right approach for HTA methodologies and processes are needed before widespread use of HTAs in the U.S. would be ethically, politically and scientifically optimal. Lacking more promising ideas, policymakers have turned to proposals, including international reference pricing, to reel in high drug prices.[21, 22] Such a "solution" will not address hospital and physician services—which account for the majority of healthcare spending[103]—and would anchor U.S. drug prices to those in other countries, implicitly tying them to the priorities, values and deliberations established in non-U.S. HTA processes.

Rather than looking to healthcare decisions made by countries with different preferences and healthcare systems, the U.S. should develop a solution that considers all areas of healthcare and meets the needs of a wide range of stakeholders and payers.[23, 104] Some may argue that our recommendations are too narrow or limited, particularly since we do not support at this time the mandatory inclusion of CEA in its current form as a function of the IHTA. We leave the CEA role to private and nongovernmental entities and anticipate that the IHTA will help improve the ability of such analyses to include relevant variables that most reflect societal value and provide additional information to complement CEA so it is not the only factor driving decisions about price and access. However, the establishment of a publicly funded, advisory-only HTA organization—that complements existing private and nonprofit organizations and focuses on identifying, synthesizing and presenting evidence on effectiveness and cost as well as data collection—would represent a significant step forward in the current U.S. healthcare landscape and have global impact. This organization not only would improve quality and transparency of HTA in the U.S., but also could lay the groundwork for decision-making in healthcare that reflects the value of technologies and therapies to patients and rewards both innovation and quality of care.

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USC SCHAEFFER CENTER-ASPEN INSTITUTE ADVISORY PANEL ON HEALTH TECHNOLOGY ASSESSMENT IN THE U.S.

The panelists were chosen to represent the stakeholders in HTA including academics, patients, industry and government. This range of viewpoints exemplifies the recommended balanced stakeholder involvement in the organization. Below we list the affiliations and financial interests of the panelists.

CO-CHAIRS

Darius Lakdawalla is director of research at the USC Schaeffer Center for Health Policy & Economics and a professor in the Sol Price School of Public Policy and the School of Pharmacy at the University of Southern California. He reports receiving research support, speaker fees, travel assistance, or consulting income from the following sources: Amgen, Biogen, Genentech, GRAIL, Edwards Life Sciences, Novartis, Otsuka, Pfizer, and the National Institutes of Health in the past three years. Dr. Lakdawalla also owns equity in Precision Medicine Group, and previously served as a consultant for them.

Peter J. Neuman is a professor and the Director of the Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies at Tufts University.

Gail R. Wilensky is an economist and senior fellow at Project HOPE. She was formerly the director of CMS, the chair of MedPAC, and served as the senior health and welfare advisor to President George H.W. Bush.

PANELISTS

Academics

Jalpa A. Doshi is a professor at the Perelman School of Medicine at the University of Pennsylvania and the Director of Value Based Insurance Design Initiatives in the Center for Health Incentives and Behavioral Economics. She reports serving as a consultant and receiving grants from biopharmaceutical companies, insurers and foundations.

Louis P. Garrison is a professor emeritus in the Department of Pharmacy and the Comparative Health Outcomes, Policy, and Economics (CHOICE) Institute at the University of Washington.

Dana P. Goldman is director of the USC Schaeffer Center for Health Policy & Economics, which sponsored this HTA panel. He is also a Distinguished Professor of Public Policy, Pharmacy & Economics at the School of Pharmacy and the Sol Price School of Public Policy at the University of Southern California. He reports receiving research support, speaker fees, travel assistance, or consulting income from the following sources: ACADIA Pharmaceuticals, Amgen, The Aspen Institute, Biogen, Blue Cross Blue Shield of Arizona, BMS, Cedars Sinai Health System, Celgene, Edwards Life sciences, Gates Ventures, Genentech, Gilead Sciences, GRAIL, Johnson & Johnson, Kaiser Family Foundation, National Institutes of Health, Novartis, Pfizer, Precision Health Economics, Roche, and Walgreens Boots Alliance in the past three years.

Joel W. Hay is a senior fellow at the USC Schaeffer Center for Health Policy & Economics and a professor in the School of Pharmacy at the University of Southern California.

Finn Børlum Kristensen is a professor for the Faculty of Health Sciences at the University of Southern Denmark.

Daniel A. Ollendorf is a professor and the Director of Value Measurement and Global Health Initiatives for the Center of Evaluation of Value and Risk in Health at Tufts University School of Medicine. He is a former employee and current collaborator with the Institute for Clinical and Economic Review (ICER).

William V. Padula is a senior fellow at the USC Schaeffer Center for Health Policy & Economics and a professor in the School of Pharmacy at the University of Southern California.

Charles E. Phelps is a professor and provost emeritus at the University of Rochester.

Mark J. Sculpher is a professor of health economics at the University of York. He reports consulting for various life science companies.

Industry and Patient Advocacy

Alan Balch is the CEO of Patient Advocate Foundation and National Patient Advocate Foundation.

Zeba M. Khan is the Vice President of Pricing and Market Access for Celgene.

Samuel R. Nussbaum is a professor of clinical medicine at the Washington University School of Medicine in St. Louis and Nonresident Senior Fellow at the Schaeffer Center for Health Policy & Economics. He was formerly the Chief Medical Officer of WellPoint/Anthem.

Dana Gelb Safran is the Senior Vice President of Value Based Care & Population Health at WELL Health, Inc.

Government

Margaret A. Hamburg is the Foreign Secretary for the National Academy of Medicine, and she previously served as the Commissioner of the FDA. She serves on a biopharmaceutical company board.

Ruth J. Katz is the Vice President and Executive Director of the Health, Medicine and Society Program at The Aspen Institute, which sponsored this HTA panel. She was formerly Chief Public Health Council with the Committee on Energy and Commerce in the U.S. House of Representatives.

Sean R. Tunis is a Principal for Rubix Health and is the former head of the health program at the Congressional Office of Technology Assessment and Chief Medical Officer for CMS. He is the past-president of Health Technology Assessment International (HTAi).

Additional Authors

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The mission of the Leonard D. Schaeffer Center for Health Policy & Economics is to measurably improve value in health through evidence-based policy solutions, research excellence, and private and public sector engagement. A unique collaboration between the Sol Price School of Public Policy at the University of Southern California (USC) and the USC School of Pharmacy, the Center brings together health policy experts, pharmacoeconomics researchers and affiliated scholars from across USC and other institutions. The Center's work aims to improve the performance of health care markets, increase value in health care delivery, improve health and reduce disparities, and foster better pharmaceutical policy and regulation.

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