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Collaborative Leadership Summit: **Designing a Framework for the Sustainability of Patient Assistance**

Phase I Report of Interactive Management Project

with



Prepared by:

Peter H. Schwartz, MD, PhD

Alexander N. Christakis, PhD



In Collaboration with:

Johanna Bell, MPH

Deputy Program Director, VIH

and

Kathie Westpheling, MPH

Associate Director, Association of Clinicians for the Underserved

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EXECUTIVE SUMMARY

This report is the result of an extraordinary gathering among individuals who met for two days to explore mechanisms to improve access to pharmaceuticals for Americans. While this is not the first such attempt, several elements mark this effort as particularly promising: It included representatives of major stakeholder groups, who came together in a structured process which not only allowed all voices to be heard but demanded that individuals clarify their intent to promote the group's understanding. Most notably, the recommendations of the group appear to be win-win options; that is, implementing a suggested action does not favor one group of stakeholders to the detriment of others.

The major focus of the effort was improving Patient Assistance Programs (PAPs) that are sponsored by many pharmaceutical companies to provide free medications to uninsured patients. These programs represent a substantial commitment by the companies and provide millions of dollars worth of medicines for people who have no other means of paying for them. In their efforts to manage these programs, companies may create eligibility requirements that make medications available to only a narrow segment of the uninsured, institute application processes that are time and labor intensive, and/or institute other mechanisms that providers experience as cumbersome. In turn, this has led to growing frustration among clinicians and patient advocates whom clamor for easier access and more consistency among the programs.

How to maintain or expand pharmaceutical company donations, recognize the industry's legitimate need to control growth of the programs, and facilitate access and use by patients and their clinicians is the challenge. As a first step, the Association of Clinicians for the Underserved (ACU) convened a workgroup that included members of industry, clinicians, federal agency representatives, and patient advocates to plan a course of action. This workgroup resulted in the convening of a Summit meeting on March 5-6, 2001. The Summit was the result of a collaboration involving the Association of Clinicians for the Underserved; the American Academy of Family Physicians; the Bureau of Primary Health Care's Office of Pharmacy Affairs, and its Quality Center, both in the US Health Resources and Services Administration; the National Committee to Preserve Social Security and Medicare (NCPSSM); and Volunteers in Health Care (VIH).

Twenty-one leaders from health care, government, and the pharmaceutical industry met for two days in Princeton, New Jersey to generate ideas for sustaining and improving access to pharmaceutical services, especially PAPs. The Summit was wholly funded by VIH through their grant from the Robert Wood Johnson Foundation.

A discussion paper was given to the participants prior to the Summit, based on interviews with a diverse group of industry executives, patient advocates, clinicians and others, as well as a limited literature review. This paper highlighted the following points:

- Healthcare providers and pharmaceutical companies often have competing perceptions of PAPs. Any attempt to improve pharmaceutical access for the uninsured must address perceptions in this area.
- Some company executives report that their PAPs are growing at approximately 30% per year, an expansion that could undermine the future stability of such programs.
- Provider complaints about PAPs often center on the administrative and logistical challenges of accessing and utilizing them. Companies point out that at least some of these requirements are necessary to block abuse and satisfy legal obligations.
- Previous attempts to develop a unified application and distribution process for PAPs have failed to attract industry support, raising questions about the viability of this approach in the future. On the other hand, centralized information sources, such as VIH's RxAssist Web site, have helped healthcare providers utilize PAP programs.
- Free samples given to prescribers have been one major source of pharmaceuticals for the uninsured. Such use, however, contradicts the main intent of providing samples and faces many challenges, including increased legal and regulatory requirements.
- Some local projects have developed ways to provide medications to the uninsured and underinsured that do not involve PAPs, although these projects are local and limited in size.
- The possibility of streamlining or simplifying the administration of PAPs attracts interest from pharmaceutical company executives, health care providers, federal programs, and patient advocates, since such changes could reduce drug company

costs, increase patient access, and improve health outcomes.

Prior to building a consensus on the most effective actions, the participants anticipated and clarified challenges in meeting the prescription needs of the uninsured, and explored how the challenges are interrelated. The participants' judgments of the relationships among the challenges produced a pattern displaying how some challenges exert influences on others. The most influential challenges are positioned at the lower levels of the tree-like pattern shown in Figure 1 (see page 6). The arrows in Figure 1 indicate how some challenges influence others; addressing challenges at the lower levels of Figure 1 will help significantly in addressing challenges at the higher levels, provided there are arrows connecting those challenges.

For example, one of the most influential challenges is Challenge #26: The philosophical conflict between health care as a right and health care as a business. According to the majority of the participants, resolving this philosophical conflict will help significantly in addressing twelve of the other challenges, as shown graphically in Figure 1 by means of the arrows directed upward from Level V.

Other important challenges fell into three major "tracks," as shown in Fig. 1. Track 1 includes four themes, of which the first two were identified as most influential. These are:

- *philosophical differences*: bridging the gap between people who conceive of healthcare primarily as a right and those who see it as a business;
- *assigning responsibility*: involving groups other than just industry;
- *samples*: reducing the use of samples for the uninsured, perhaps through improving alternative sources;
- *rapid growth of PAPs*: controlling growth of PAPs.

Track 2 focuses on the need to address:

- competition among pharmaceutical companies;
- conflict between company need for control and clinician need for consistency;
- conflict between prescriber satisfaction and checking patient qualifications.

Track 3 emphasizes the high cost of medications and the need to consider ways

to limit access to control costs. Track 4, with only one challenge associated with it, speaks to the need for data on the magnitude of the problem.

By the Summit's conclusion, participants had proposed 44 possible action steps. Through a series of individual votes and small team scenarios, as shown in Table 3 (see page 7), the participants identified six actions that would be the most effective in addressing the challenges identified in meeting the prescription needs of the uninsured. These actions fell into three categories:

1) Sharing Responsibility:

- *Form a taskforce to seek ways that all the components involved in providing the PAP can contribute to the actual costs of the program.*
- *Explore alternative PAP models whereby patients an/or providers, i.e. stakeholders, pay a nominal price to cover actual manufacturing and distribution costs.*

2) Improving PAPs:

- *Establish a stakeholder working group to develop concrete proposals for making PAPs more efficient for all parties involved.*
- *Organize a pharmaceutical-industry-wide group with people at various organizational levels, and areas of expertise, to come together to discuss the challenges and possible solutions for PAPs.*

3) Laws and Regulation:

- *Seek government advisory opinions clarifying definitively PAP liability risks especially for manufacturers under the Prescription Drug Marketing Act (PDMA), anti-trust, anti-kickback, etc.*
- *(Seek) congressional action to redefine regulations and law that interfere with patient access to medication.*

Future collaborative action to sustain pharmaceutical access for the uninsured should give serious consideration to the six most effective actions within the three categories described above.

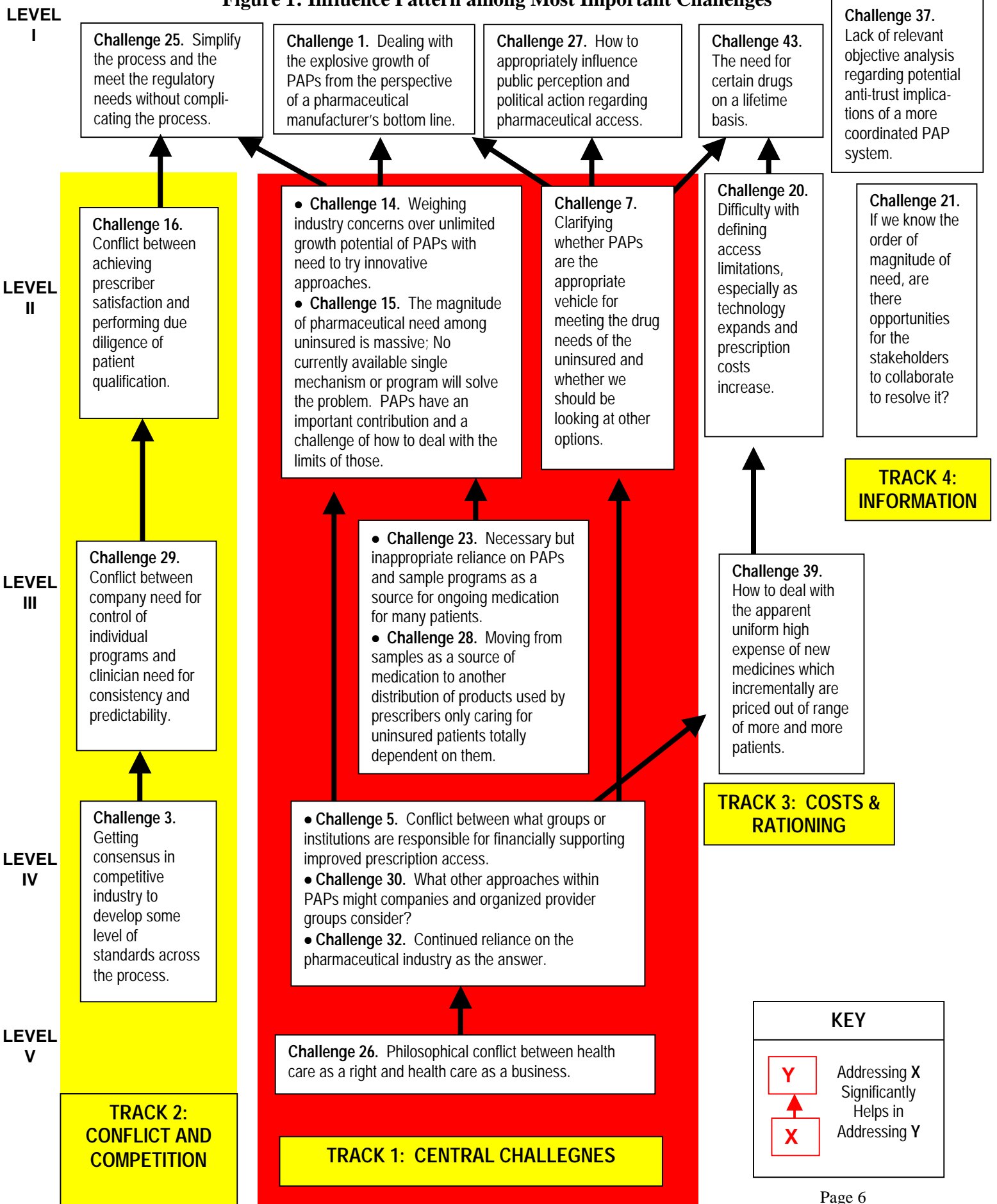
An additional action item, raised in two separate areas and generating considerable discussion and support, focused on testing innovative models for improved efficiencies within both PAPs and the use of sample programs. One suggested “exploring cost sharing models that can be managed with minimal regulation and paperwork, and

shared recognition” while the other recommended “at selected clinics and one or more pharmaceutical manufacturers, establish a pilot model for addressing prescription product needs of indigent patients through shared responsibility and collaborative process.”

Participants seemed to feel that a diverse task force of stakeholders, empowered to test approaches palatable to both industry and clinician groups and within the parameters of federal regulations, could identify and inspire new models suitable for adoption on a larger scale. Such innovations, whether incremental or systemic in scope, could go far toward helping to meet the prescription assistance needs of the uninsured.

It is important to recognize the discipline and creativity of Summit participants in addressing this complex issue from a variety of perspectives through a systematic process for dialogue. With the further involvement of those individuals and organizations not able to participate in the meeting, we hope to expand upon this base of knowledge and link it to specific actions that will maintain and improve these vital patient assistance programs to the satisfaction of all parties.

Figure 1: Influence Pattern among Most Important Challenges



**Table 3: Voting Results on Action Options for Meeting the System of Challenges
(Individual Votes and Team Scenarios Votes)**

Team Scenario	Individual Votes	Action Option:
All 3 Teams	(4) *	(1 - Action Option) FORM A TASK FORCE TO SEEK WAYS THAT ALL THE COMPONENTS INVOLVED IN PROVIDING THE PAP CAN CONTRIBUTE TO THE COST OF THE PROGRAM (Cluster #1) .
All 3 Teams	(6) *	(25 - Action Option) ESTABLISH STAKEHOLDER WORKING GROUP TO DEVELOP CONCRETE PROPOSALS FOR MAKING PAPS MORE EFFICIENT FOR ALL PARTIES INVOLVED (Cluster #2) .
All 3 Teams	(2) *	(32 - Action Option) DEVELOP A PLAN AND A BUDGET FOR TACKLING THESE MANY SUGGESTIONS (Cluster #8) .
2 Teams	(8) *	(37 - Action Option) EXPLORE ALTERNATIVE PAP MODELS WHEREBY PATIENTS AND/OR PROVIDERS PAY A NOMINAL PRICE TO COVER ACTUAL MANUFACTURING AND DISTRIBUTION COSTS (Cluster #1) .
2 Teams	(4) *	(8 - Action Option) SEEK GOVERNMENT ADVISORY OPINIONS CLARIFYING, DEFINITELY, PAP LIABILITY RISKS ESPECIALLY FOR MANUFACTURERS UNDER PDMA, ANTITRUST, ANTIKICKBACK, ETC. (Cluster #3) .
2 Teams	(5) *	(22 - Action Option) CONGRESSIONAL ACTION TO REDEFINE REGULATION AND LAW THAT INTERFERE WITH PATIENT ACCESS TO MEDICATIONS (Cluster #6) .
1 Team	(7)	(13 - Action Option) ORGANIZE A PHARMACEUTICAL INDUSTRY-WIDE GROUP WITH PEOPLE AT VARIOUS ORGANIZATIONAL LEVELS AND AREAS OF EXPERTISE TO COME TOGETHER TO DISCUSS THE CHALLENGES AND POSSIBLE SOLUTIONS FOR PAP (Cluster #2) .
1 Team	(4)	(2 - Action Option) DEVELOP ALTERNATIVE PAP PROCESSES FOR PRIVATE PHYSICIAN OFFICES AND LARGER ORGANIZATIONS SUCH AS FREE CLINICS (Cluster #2) .
1 Team	(4)	(11 - Action Option) CREATE A BEST PRACTICE PRESCRIPTION CARD MODEL FOR PROVIDING NECESSARY MEDICINES VIA COMMUNITY PHARMACIES THROUGH SHARED RESPONSIBILITY (Cluster #2) .
1 Team	(4)	(7 - Action Option) EXPLORE COST SHARING MODELS THAT CAN BE MANAGED WITH MINIMAL REGULATION AND PAPERWORK WITH SHARED RECOGNITION (Cluster #1) .
1 Team	(3)	(3 - Action Option) AT SELECTED CLINICS AND ONE OR MORE PHARMACEUTICAL MANUFACTURERS ESTABLISH A PILOT MODEL FOR ADDRESSING PRESCRIPTION PRODUCT NEEDS OF INDIGENT PATIENTS THROUGH SHARED RESPONSIBILITY AND COLLABORATIVE PROCESS (Cluster #1) .
1 Team	(2)	(12 - Action Option) EXPANDING THE USE OF NOMINAL "PRICE" OPTIONS (Cluster #1) .
1 Team	(2)	(9 - Action Option) DEVELOP A MINDSET AMONG STAKEHOLDERS THAT PHARMACEUTICAL ACCESS NEEDS TO BE A SHARED RESPONSIBILITY, INDUSTRY, GOVERNMENT AND OTHERS (Cluster #1) .

* These six action options are identified in Figure 2 as those selected for the Consensus Action Scenario.