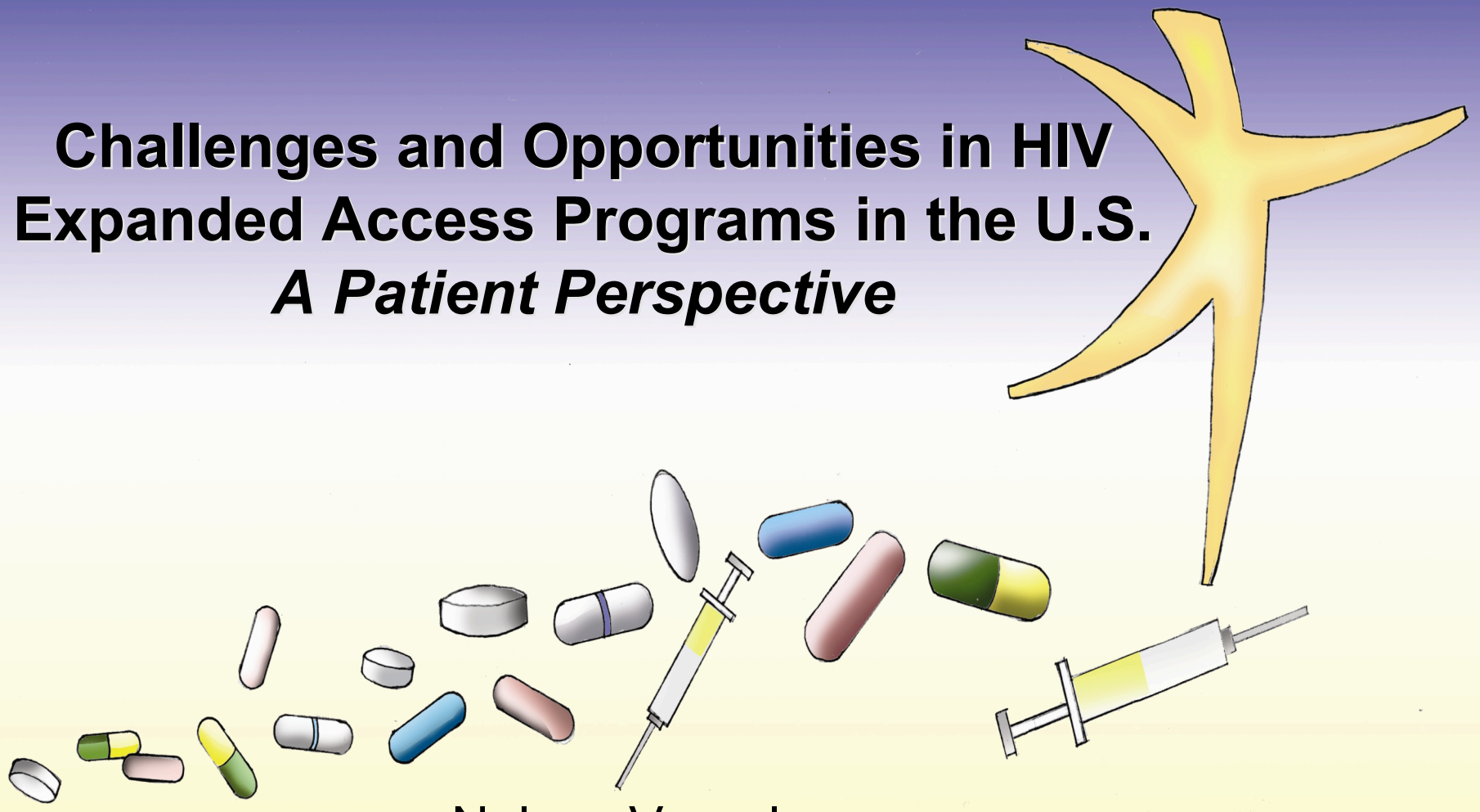
Challenges and Opportunities in HIV Expanded Access Programs in the U.S.
A Patient Perspective



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2007- EAP Improvements

- **With community input, companies are collaborating better to allow simultaneous use of several investigational agents in phase III and/or EAP's**
  - **TMC 114 EAP + TMC 125 phase III (DUET study)**
  - **TMC 114 EAP + MK 518 phase III (Benchmrk study)**
  - **MK518 EAP + TMC 125 EAP (present)**
  - **Coming up: Maraviroc EAP+ MK 518 EAP+ TMC 125 EAP**
- **Second wave of HAART: three drugs in existing classes (Aptivus, Prezista, TMC 125) and three in new classes (Fuzeon, MK 518, Maraviroc) make it possible to construct viable regimens for the first time in years**
- **There seems to be a trend towards reimbursement for nurse/physician time. No standard is set yet. No clear FDA regulations on this item**
- **There is more awareness about the risks of virtual monotherapy among patients and clinicians, although this problem is far from over**
- ***A* company is developing more user friendly EAP web sites to allow for EAP inclusion/exclusion and site information for patients and clinicians**
- ***A* company is reaching out to "non-traditional" sites that may not have prior EAP experience. This approach may improve access to uninsured (Ryan White Title I, II and III) and underserved populations.**
- **Companies are inviting contract research organizations to community review meetings**

2007- Challenges

- **Geographical limitations impede access for patients in small cities.**
- **Many doctors and clinics refuse to be part of EAP's due to cost and manpower requirements. Several cocurrent EAP's may burden research nurses' time. Complete patient histories are required (many patients with over 15 years of accumulated medical histories).**
- **Lag time in PK/interaction studies. TMC 125 + MK 518 interaction data were not available in the first 5 months of both companies' EAP's.**
- **Some companies do not list EAP sites in clinicaltrials.gov or their own web sites. Some doctors may not refer patients to EAP sites due to fears of losing patients to those practices**
- **Advertising of EAP's is not optimal due to companies' concerns about pre-approval marketing regulations and other issues**
- **Lack of resistance tests at EAP entry may increase risks of virtual monotherapy for patients who may start an investigational drug in existing drug classes (example: TMC 125 EAP + TMC 114, TMC 114 EAP + MK 518)**
- **Exclusion criteria may exclude patients with the most need**
- **EAP consent forms are not consistently reviewed by community treatment advocacy groups**
- **Do not forget the second-wave non-responders!**