A safe, affordable way to improve care:
Repurpose approved UCAs for whole-body use

Presentation to Reagan-Udall Foundation for the FDA
Drug Repurposing: Considerations for Selection Criteria and Prioritization

Assigned topic:
"Examples of successful prioritization approaches from other programs or jurisdictions that could be adapted"

Hybrid Public Meeting
August 5, 2026

https://us06web.zoom.us/j/82028040286

Statement on behalf of the International Contrast Ultrasound Society - a grassroots nonprofit organization representing doctors, sonographers, scientists and patients in 90 countries:

Thank you for the opportunity to discuss the repurposing of ultrasound contrast agents (UCAs) – which are drugs that enhance diagnostic ultrasound scans. Their use changes management and outcomes for patients suffering from cancers and diseases, including rare diseases, throughout the body .

At present adult indications are limited to the heart and liver -- but benefits are much broader because a single IV injection shows perfusion of all organs.

UCAs are ideal candidates for repurposing because:

1. Safety is well established in clinical trials and scientific literature.

2. Clinical practice guidelines recommend uses throughout the body.

3. Some patients have **no other option for advanced imaging**. For example, patients who are kidney-impaired or pregnant may not be

candidates for contrast-CT or MR because those contrast agents can damage kidneys, cross the placenta, and present risk of gadolinium deposit in the brain.

4. Because UCAs provide **reliable results in real-time**, they reduce the need for downstream tests and procedures -- lowering costs and risks.

5. Limiting use to the heart and liver is clinically illogical. If a radiologist examines the liver, for example, and spots a suspicious mass on the kidney or spleen, it makes sense to move the transducer and follow the disease.

6. And ultrasound is more affordable and more widely available than MR and CT.

That's why UCAs are often used for whole-body applications in Europe and elsewhere, **without raising safety concerns**.

Unfortunately, in the US, our organ-specific approval process can be cost-prohibitive and burdensome.

We believe UCAs are low-hanging regulatory fruit and should be one of the first drugs considered for repurposing. They are safe, affordable, and have the potential for high impact on care and outcomes involving cancers and diseases throughout the body.

Thank you.

Agenda

10:30AM	**Welcome** **Susan C. Winckler, RPh, Esq.,** CEO, Reagan-Udall Foundation for the FDA
10:35AM	**Opening Remarks** **Brian Fahey,** Senior Advisor, Immediate Office of the Commissioner, FDA
10:40AM	**FDA's Drug Repurposing Efforts** **Marta Sokolowska, PhD,** Deputy Center Director for Substance Use and Behavioral Health - Center for Drug Evaluation and Research (CDER), FDA
10:50AM	**Session 1: Snapshots of Repurposing Efforts** **Mitra Ahadpour, MD,** Deputy Director - Office of Translational Sciences, CDER, FDA **Matt Hall, PhD,** Scientific Director, National Center for Advancing Translational Sciences **Heather Stone, MPH,** Health Science Policy Analyst - Office of Medical Policy, CDER, FDA
11:15AM	**Session 2: Selection Criteria and Prioritization** **Caroline Huang, PhD,** Supervisory General Health Scientist - Controlled Substances Initiatives, CDER, FDA *Reactor Panel:* **Susan Cantrell, RPh, MHL, CAE,** CEO, Academy of Managed Care Pharmacy **Pam Gavin, MBA,** CEO, National Organization for Rare Diseases **Huong Huynh, PhD,** Director of Regulatory Science, Critical Path Institute **Janet Woodcock, MD,** Former FDA Acting Commissioner
12:15PM	**Break for Lunch** *Lunch on your own. A list of local eateries will be available.*
1:15PM	**Session 3: Evidence and Submission Expectations** **Sundeep Agrawal, MD,** Associate Director of Clinical Programs, Oncology Center of Excellence, FDA **David Fajgenbaum, MD, MSc, MBA,** Co-Founder and President, Every Cure *Reactor Panel:* **Amy Abernethy, MD,** CEO, Highlander Health **Marie Bradley, PhD, MPharm** Senior Advisor RWE - Office of Medical Policy, CDER, FDA **Emily Freilich, MD,** Director - Division of Neurology, Office of New Drugs, CDER, FDA **Donald Lo, PhD,** Director of Medicines Development and Scientific Lead, REMEDi4ALL
2:15PM	**Session 4: Federal Partner Discussion** *Panelists:* **Andrew Brack, PhD,** Program Manager - Proactive Health Office, ARPA-H **Christine Colvis, PhD,** Director of Drug Development Partnership Programs, National Center for Advancing Translational Sciences **Shari Ling, MD,** Deputy Chief Medical Officer, Centers for Medicare and Medicaid Services **Marta Sokolowska, PhD,** Deputy Center Director for Substance Use and Behavioral Health - CDER, FDA **Danielle Turley, PhD,** Acting Director - Division of Regulatory and Quality Affairs, BARDA

3:15PM	Public Comment Individuals who registered in advance to provide public comment will have 2.5 minutes for remarks No direct questions will be posed to speakers or panelists
5PM	Adjourn

This project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an award of $118,960 in federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.