



EMPOWERMENT FRAMEWORK

CONFLICTS OF INTEREST



CONCERNS

Conflicts Compromise
Health and Trust

SOLUTIONS

How to Achieve Health and Trust

IDENTIFY PROBLEMS: ARE THE SOLUTIONS ENOUGH?

- Transparency and Disclosure
- Reflexivity
- Checks on bias
- Financial or Other



STAKEHOLDERS

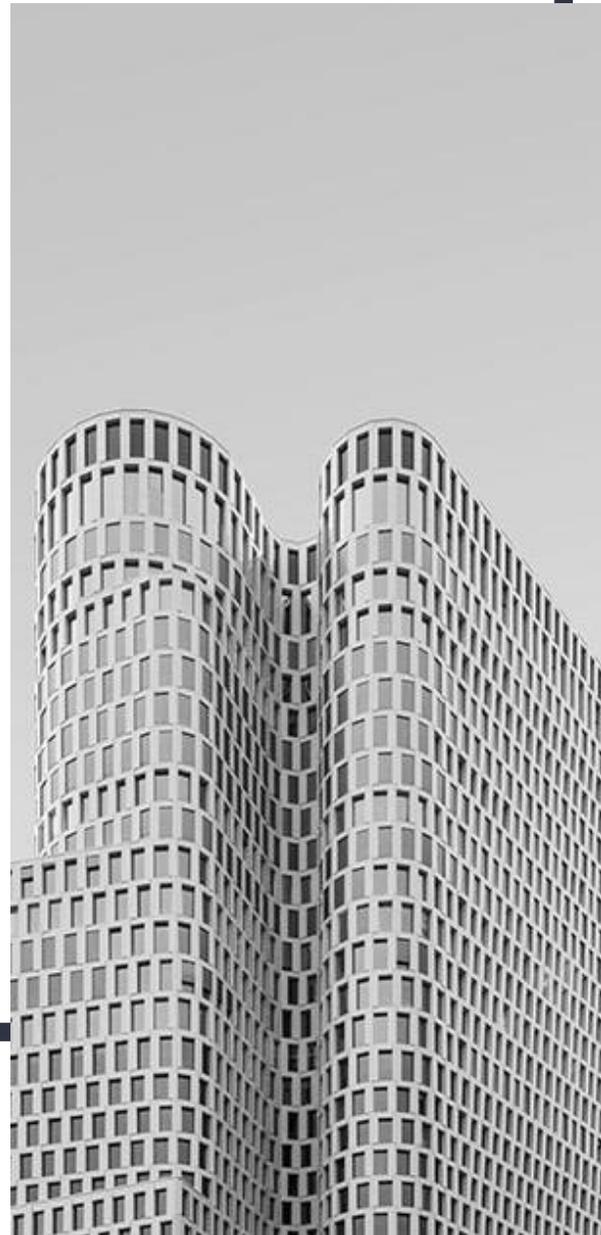
M O R A L V A L U E O F S T A K E M A T T E R S

Recognizing that the people whose health, well-being, or rights are affected or could be affected by the conflict are the stakeholders whose stake is generally bodily or personal, and secondarily financial. The stake of the corporation or government as stakeholders varies, is not bodily, and is usually foremost financial, making ethical claims arguably weaker.

DO ACADEMIC MEDICAL CENTERS DO TOO MUCH?

RESEARCH

- Clinical research is the cornerstone of drug development and approval.
- Relationships with pharmaceutical companies to develop and manufacture lead to treatments, help the sick, and hasten product development.
- Clinical trials are regulated but IRBs tend to oversee the inhouse approval process.



CLINICAL CARE

- Clinical trials are an on-the-ground event. Often therapeutic to the patient despite sign-off on it being research.
- Is the clinician making money from the research relationship with the pharmaceutical company?
- There are inherent conflicts of interest when clinicians recommending expensive treatments are researchers and part of the deal with pharma.



WHEN IS DISCLOSURE ENOUGH?

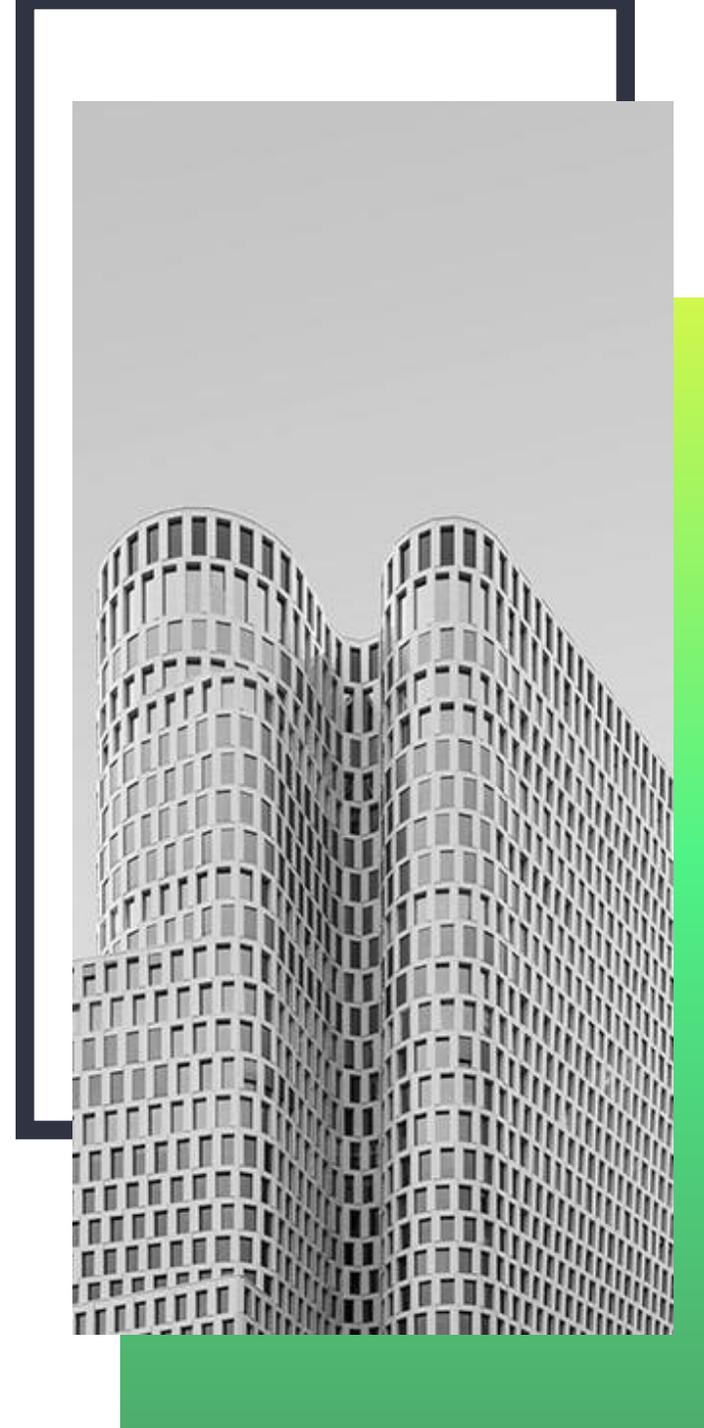
MORAL VALUE OF THE SUBJECT OF THE CONFLICT

A conflict of interest that leads to or is an inevitable part of the drug discovery process may be managed rather than prohibited if conditions ensuring good faith are met. A more rigorous analysis of the data during an approval process might be able to counteract the potential that the conflict of interest leads to shoddy clinical trials, fraudulent behavior, or any shortcuts that could threaten the safety or efficacy of the new treatment.

EDUCATE MEDICAL STUDENTS

OBJECTIVITY

- Are students receiving objective information?
- Are professors objective-is true objectivity impossible?
- Professors need to be experienced as clinicians or researchers.



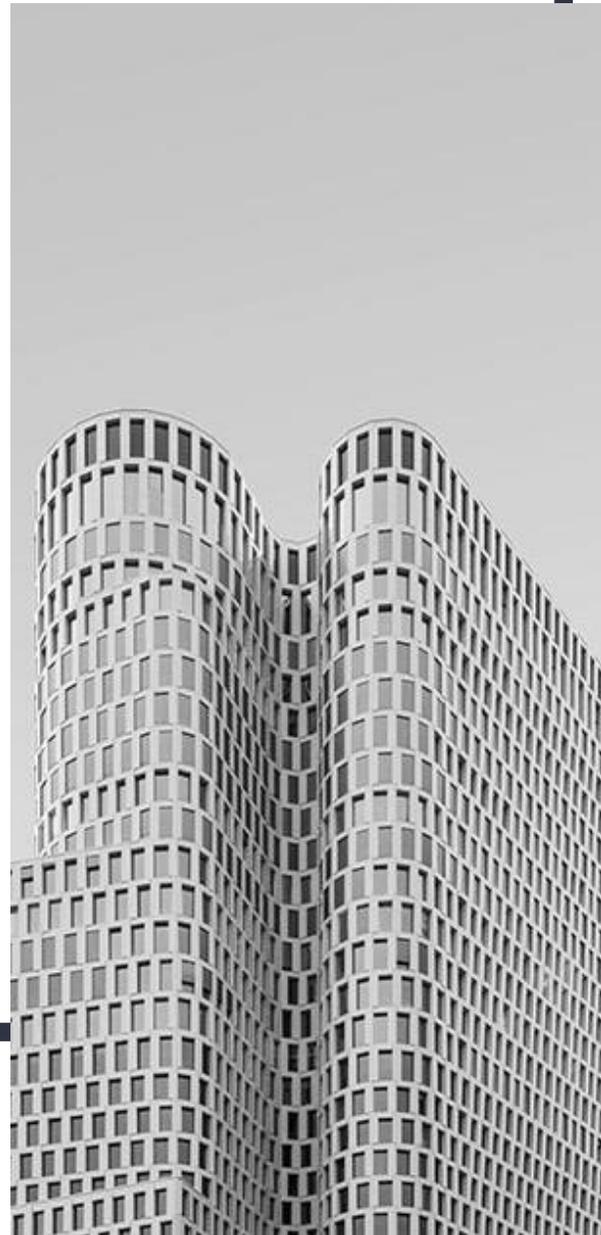
ORGANIZATION HEALTH CARE VALUES

- How are the organization's possible biases, research relationships, bedside conflicts reflected in the medical education?

MISSION CREEP: AN ALIGNMENT OF GOALS

BIG PHARMA

- Goals are profit driven, create shareholder value, increase output.
- There is often an authentic mission to cure, heal, or treat, but fraud reveals that is not always the case.
- Now we observe patient reps, etc. as if access is part of the mission, yet the ability to have an employee truly represent a patient is complex.



ACADEMIC MEDICAL CENTERS

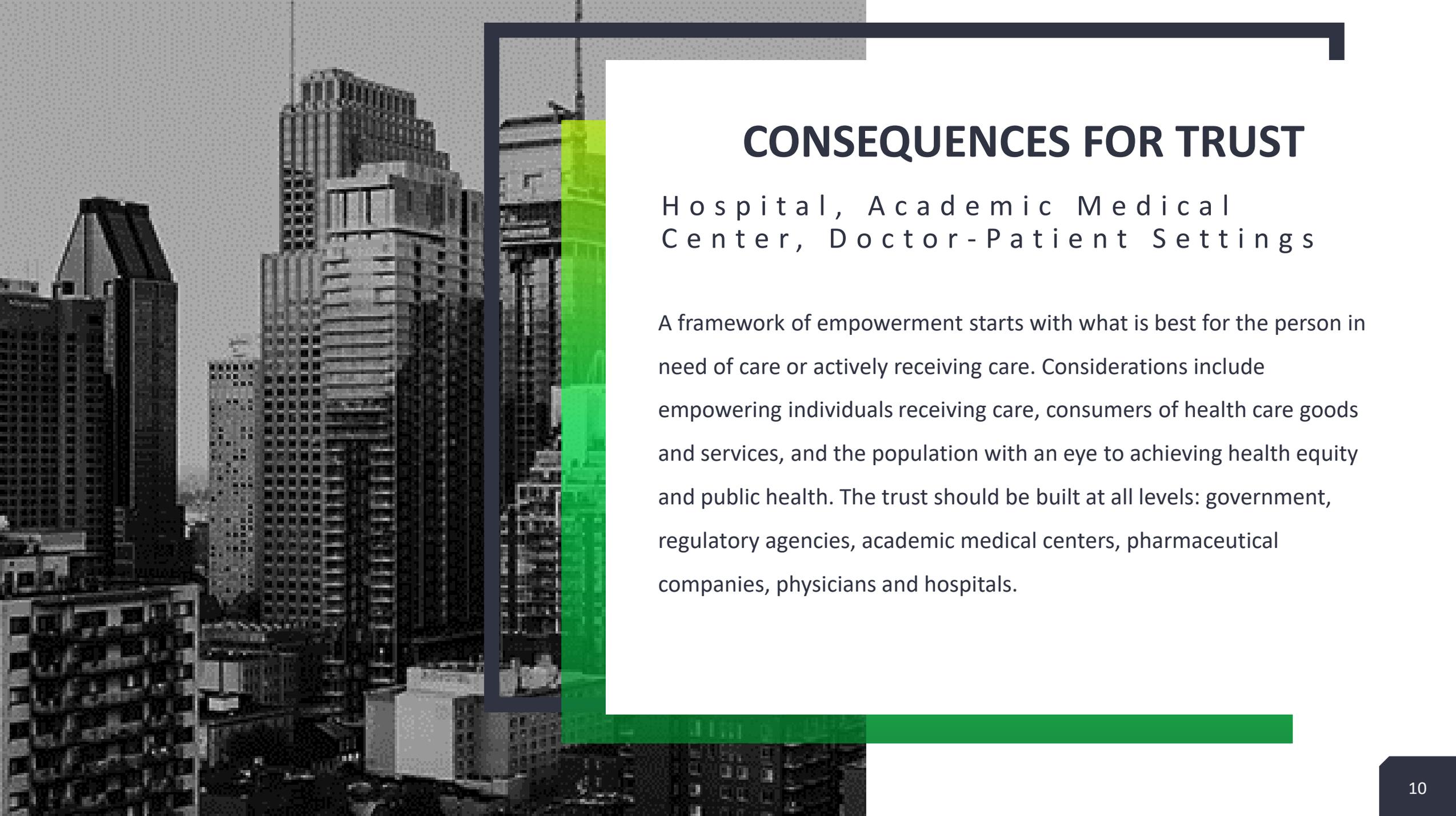
- Educate, treat, and research.
- Now the missions has extended to create options, cures, treatments through partnerships with pharma.
- The financial goals are blended by the arrangement. Any researcher's interests may align explicitly with pharmaceutical corporate interests.



FDA, NIH, CONGRESS

Their conflicts of interest could be prohibited

Because the role in fostering innovation is different and ancillary to a regulatory role, financial conflicts should be prohibited in the FDA and Congress. People at the NIH benefiting financially from companies whose products are in NIH clinical trials is also avoidable. Products subject to FDA approval should also not have any potential to generate money for those approving them. The revolving door (hiring of people who worked in industry), investment opportunities in novel drugs, and certain stock ownership impact public trust. Disclosure by those meant to be gatekeepers is not enough.

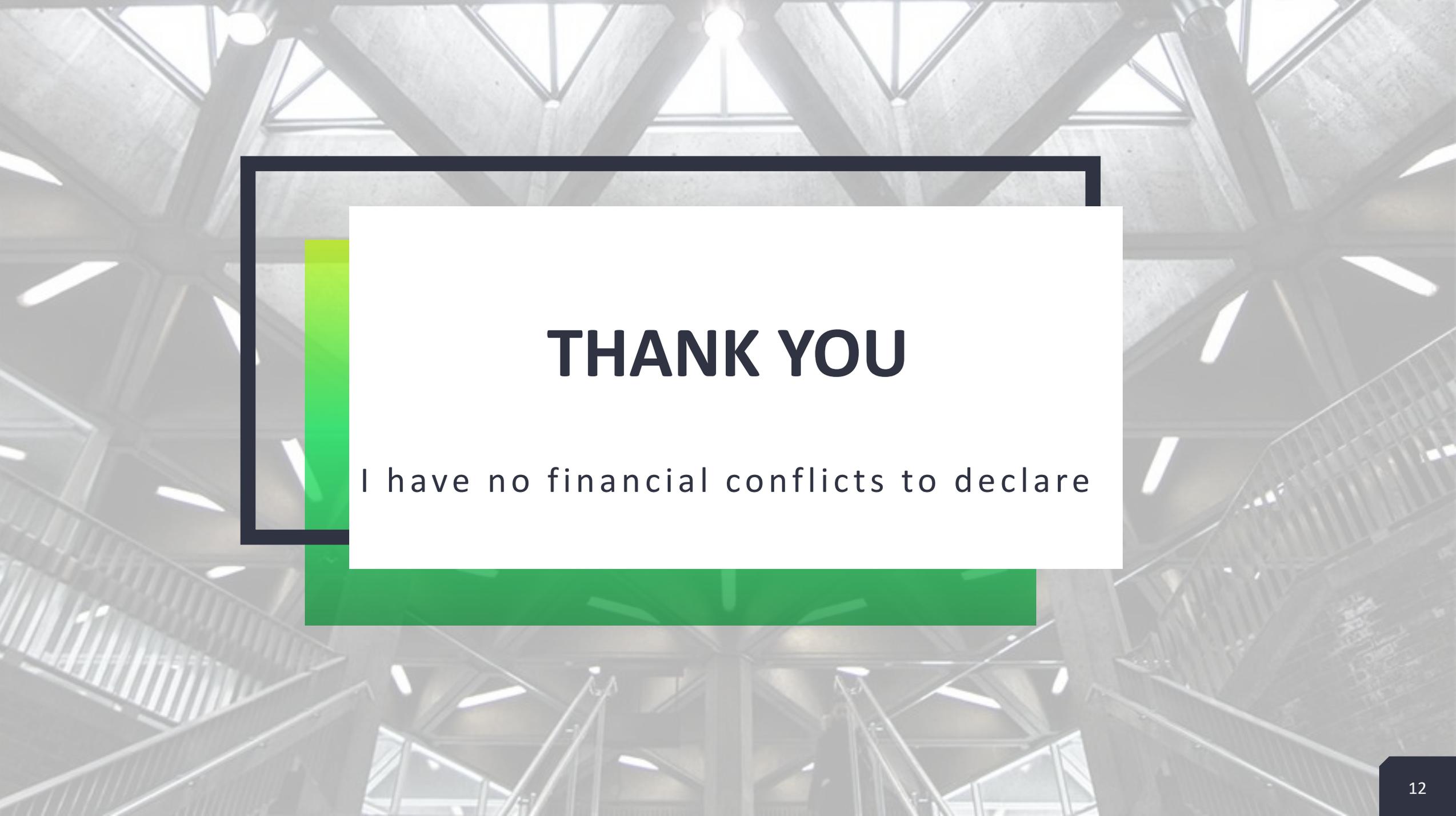


CONSEQUENCES FOR TRUST

Hospital, Academic Medical
Center, Doctor-Patient Settings

A framework of empowerment starts with what is best for the person in need of care or actively receiving care. Considerations include empowering individuals receiving care, consumers of health care goods and services, and the population with an eye to achieving health equity and public health. The trust should be built at all levels: government, regulatory agencies, academic medical centers, pharmaceutical companies, physicians and hospitals.

Oversight Framework: Conflict of Interest	Goal: protecting those vulnerable to conflicts, leveling the power dynamic. Discern when to prohibit, when to disclose and manage, financially distance the stakeholders, or when to sanction violations based on behavior, Benefits for stakeholders	Fact Pattern: A doctor who is a researcher worked on a cancer treatment and owns stock in the company that developed it. The person needing care wants to pursue an alternative with slightly lower efficacy and much more data.
Identify the Problem	What is the nature of the conflict—financial, ambitious, ability to influence a care recommendation. Person-centered approaches should protect the person in need of care.	We are uncertain whether there are enough protections in place to negate the conflict. We are unsure whether forgoing the possibly more efficacious choice will be good or bad.
Stakeholders LOOK TO WEIGH THE MORAL VALUE OF THE STAKE	Broadly analyze who could be affected by a solution. Person-centered care framework applies as well. Any person receiving a drug, the public, companies producing drugs, all people who could benefit from the drug—relationships allow drug development	All of those (currently and in the future) wanting access to the treatment, the pharmaceutical company, the doctor who is also a researcher, the person receiving care
Ethical Issue	Is disclosing the conflict like not having a conflict at all? Does the doctor have a duty to provide the other product? Prevent future conflicts of interest. Is the conflict avoidable—should it be prohibited? Is the conflict manageable? Who decides? Is the arrangement essential to innovation?	Should she switch doctors and then objectively weigh her options? Practical and theoretical. Prevent big picture problems.
Identify and weigh the Benefits	Objective and subjective components. Are some of the issues also contributors to innovation and quicker pharmaceuticals on the market. Weighing.	Academic medical centers contribute to clinicians doing research. Partnerships with pharmaceutical companies are closer to the patient. An upstream change could end this type of conflict.
Think Critically @ Macro and Individual Levels	Autonomy, right to try, trust and knowledge asymmetry, Is in-house oversight enough? Is there any way to create distance – can research be done by a team that does not do clinical care? Research can then collaborate with pharma. Upstream AMC structure feeds the issues. Remember the value of public trust, trust in the doctor and hospital.	Personal autonomy, corporate freedoms, weigh stakeholder’s interests (personal or financial)



THANK YOU

I have no financial conflicts to declare