

Navigating Policymaking Mindsets: A SciPolComm Worksheet (Front)

YOUR POLICY IDEA, ROUGHLY:

Clinics providing stem cell treatments in our state must prominently post signage and written disclaimers to inform patients that treatments have not been approved by FDA, if that is the case.

1. Roughly write out a science policy idea in the box to the left.
2. Consider your idea against the mindset of each “policymaking character” — what they care about, what is within their power, what opposition exists, and if there is critical mass or opportune timing.
3. Summarize your notes using the seven boxes on the back page.

GOVERNOR	BUDGET	AGENCIES	LEGISLATORS	COURTS
<p><i>Do They Care About This Issue?</i> Governor is a longtime supporter of stem cell research.</p>	<p><i>Are There Competing Expenses?</i> Asking private clinics to post informational signage and disclaimers in writing will not incur costs and will not affect State Budget.</p>	<p><i>Who Implements and How?</i> California Medical Board has jurisdiction over licensing and fines. Policy may add additional work burden and new tracking workflows.</p>	<p><i>Any Champions or Opposers?</i> Champions: State Legislators who want positive growth for biotech and medical treatment initiatives, and prevent fraud. Opposers: Unsure. Even those opposed to stem cells may agree with need to prevent fraud in health care.</p>	<p><i>Ongoing or Potential Challenges?</i> Therapies in question are regulated by Federal government (FDA) so any challenges and uncertainties are at that level. Nothing at state courts level.</p>
INDUSTRY & INSTITUTIONS	THE MEDIA	CONSTITUENTS	SOCIETY	SCIENTISTS
<p><i>Any Champions or Opposers?</i> Biotech industry and medical providers have interest to grow business and root out frauds. Some may push back if disclosure affects public perception over experimental treatments.</p>	<p><i>Is This Issue a Visible Topic?</i> Stem cell therapies not well explained by media. Still a scary and touchy topic. Media likes news about avoiding fraud and consumer protection.</p>	<p><i>Do They Care About This Issue?</i> Some voters are vocal advocates for experimental treatments, especially rare diseases. Some voters opposed to stem cell research and therapy. (Some equally distrusting of FDA) Voters like consumer protection measures in general</p>	<p><i>Is the Time Ripe for Change?</i> Stem cell therapy is slowly emerging in popular understanding. Still public hesitancy and poor understanding of what therapies entail. But people know it exists and work is happening -- and new therapies emerging.</p>	<p><i>What Is the State of the Science?</i> National Academies is aware of problem of unproven therapies. Regulation of therapies continues to be developed. Researchers and clinicians equally want to preserve trust and target unscrupulous providers and untested claims.</p>

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POTENTIAL CHAMPIONS

Think Access, Money, Relationships, Publicity, Communication

- Gene therapy researchers
- Research universities
- Life sciences industries and companies
- Voters with health issues that require new and emerging treatments.
- Governor
- Consumer protection advocates

POTENTIAL OPPOSITION

Think Access, Money, Relationships, Publicity, Communication

- Some supporters of more experimental therapies?
- People who are opposed to all kinds of stem cell research and therapy.

STRENGTHS

What's Great About This Idea?

It's a low-hanging fruit: very easily implementable.

Very simple and clear ruling that punts details to another body (FDA).

WEAKNESSES

What Needs Work?

Doesn't do much else.

Relies on consumers and professionals for monitoring, reporting, and enforcement of violators.

COSTS

Are Its Costs Prohibitive?

Costs nothing to the state to implement.

Minimal cost to life sciences industry.

Minimal cost to clinics.

Minor costs to take new types of violation reports but procedures already exist.

OPTICS

Does This Idea Look Good on TV?

Government looks good keeping eye on new and unproven science.

Government looks good protecting consumers and patients.

PUBLIC SENTIMENT

Do Constituents Care About This?

It's not high on everyone's radars. Stem cell opposition is waning anyways.

Overall will not raise eyebrows, and small subset of advocates will appreciate the policy.

4. Based on your notes, assess the viability of your policy idea:

- NO, this idea is not worth proposing at all.
- NO, this idea currently has no easy path to acceptance.
- NO, but we can adjust the idea that may result in an easier path.
- YES, this idea is worthwhile and there is a navigable path to acceptance. Let's adventure!

YOUR POLICY IDEA, ROUGHLY (INCLUDE ANY ADJUSTMENTS):

UNCHANGED: Clinics providing stem cell treatments in our state must prominently post signage and written disclaimers to inform patients that treatments have not been approved by FDA, if that is the case.

(IRL: California S.B. 512 Hernandez, signed into law in 2017!)