



Issues Management Demystified.

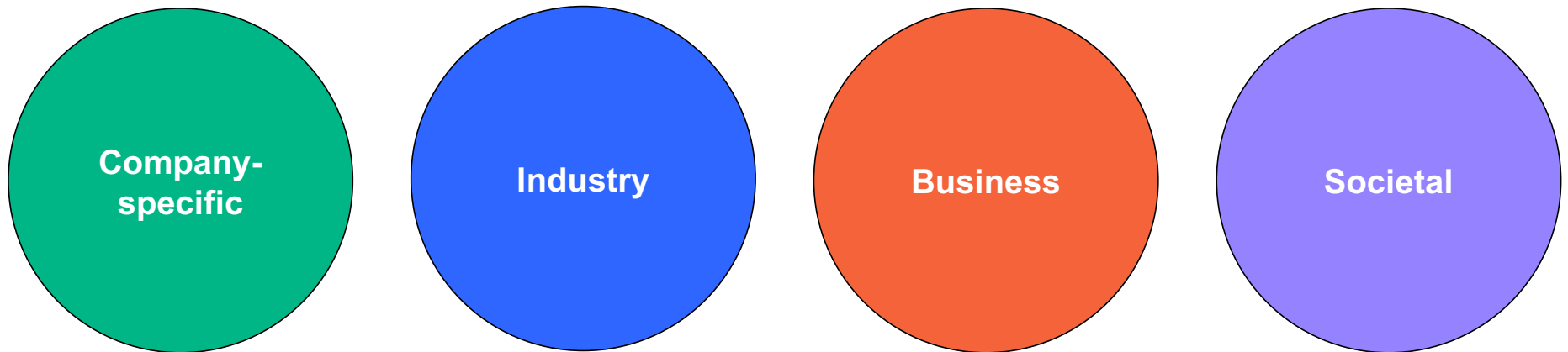
Callie Briese
April 1, 2021

Start at a high level

1. Understand your company's risk appetite
2. Matrix to the Risk Management process
3. Establish guardrails and escalation protocol



Identify and map your potential issues



Know your key stakeholders

Workforce

Key considerations:

- How will the workforce perceive this issue?
- How broadly do you need to communicate about the issue?
- Will communicating about the issue bring clarity or raise visibility?

Key internal colleagues

Key considerations:

- Who needs to understand and help inform the response?
- Who will deliver messages to which audiences?
- Are there domino effects not yet considered?

Executive leaders

Key considerations:

- How involved do they want to be?
- How often do they want to be updated?
- What is their perception of the issue?

Front-line workers

Key considerations:

- What is the likelihood they'll receive questions about an issue?
- Are they equipped with talking points?
- What are they hearing?

Media

Key considerations:

- Has the issue received media attention lately?
- How will your friendlies react?
- Is the topic gaining traction on social media?

Elected officials and regulators

Key considerations:

- Is the issue related to any current legislation? Regulation?
- Is the issue related to any recent conversations?
- Is the issue related to any campaign priorities? For whom?
- What are the regulatory requirements around notifications?

Customers

Key considerations:

- How will clients react if they learn about the issue?
- Are there particular clients who are more affected?
- Are people/clients talking about it on social media?
- Are customers contacting customer interaction centers?

Allies

Key considerations:

- Are others in your industry affected by this issue?
- Are trade groups responding?
- How will your key partners perceive this issue?

Create your plan, then practice!

1. Build muscle memory
2. Stay connected to internal partners
3. Build and reinforce external relationships
4. Establish agency partners

Monitor and respond appropriately



Monitoring tools

- Social media
- Media (including the trades!)
- Call Center volumes



Response channels

- Social media
- Customer relationship owner
- Client satisfaction department



Don't overreact!

Build your reputation

- What do you want to be known for?
- Who will come to your defense?
- How deep is your reservoir of good will?

Measurement

Short-term

Quantitative

- Social media frequency
- Social media sentiment
- Call Center volumes
- Media coverage

Qualitative

- Call Center feedback
- Employee feedback
- Feedback from Centers of Influence

Long-term

Quantitative

- Social media sentiment trends

Qualitative

- Reputation survey (3-5 years)





Thank you



LaVoieHealth**Science**
Strategic Communications

Issues Management Demystified Workshop

Donna L. LaVoie, CEO

March 31, 2021



My Perspective and Why

- I run a specialized integrated agency in health and science innovation
- Our clients are either:
 - Emerging companies
 - Or, growth companies in the process of commercializing
 - Private and public entities, but investors are always a key audience
- Our client work is full of issues management and crisis due to the nature of the business models, regulatory environment (SEC and FDA, EMEA) and risk associated with clinical development
- These are usually complex communications challenges



Key Audiences to Consider for Issues Management Plan

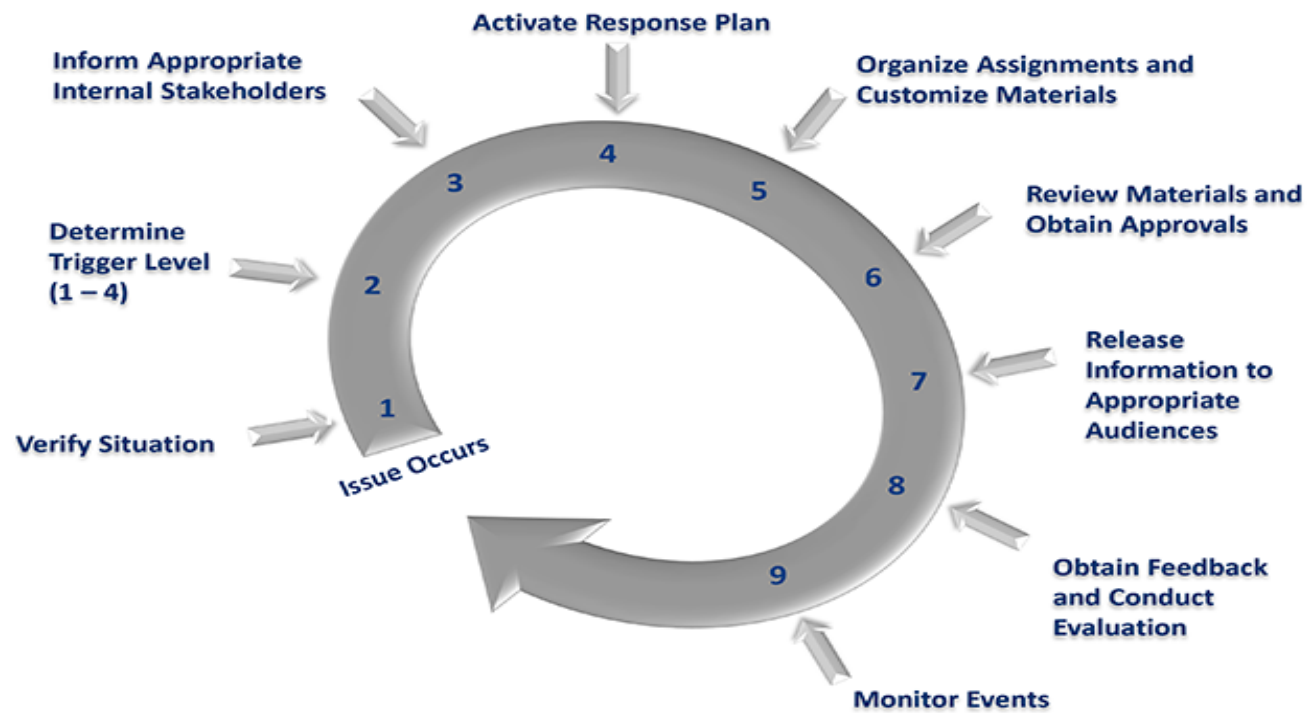
KEY AUDIENCES TO CONSIDER FOR ISSUES MANAGEMENT PLAN



- Establish client's key audience for issues is paramount in our issues plan
- Earlier stage companies main focus includes: investors, media and partners, industry
- Later stage commercial companies expands to governments (US/EU), regulatory bodies (US, EU, Asia), advocacy (in particular patient groups), industry organizations, professional societies

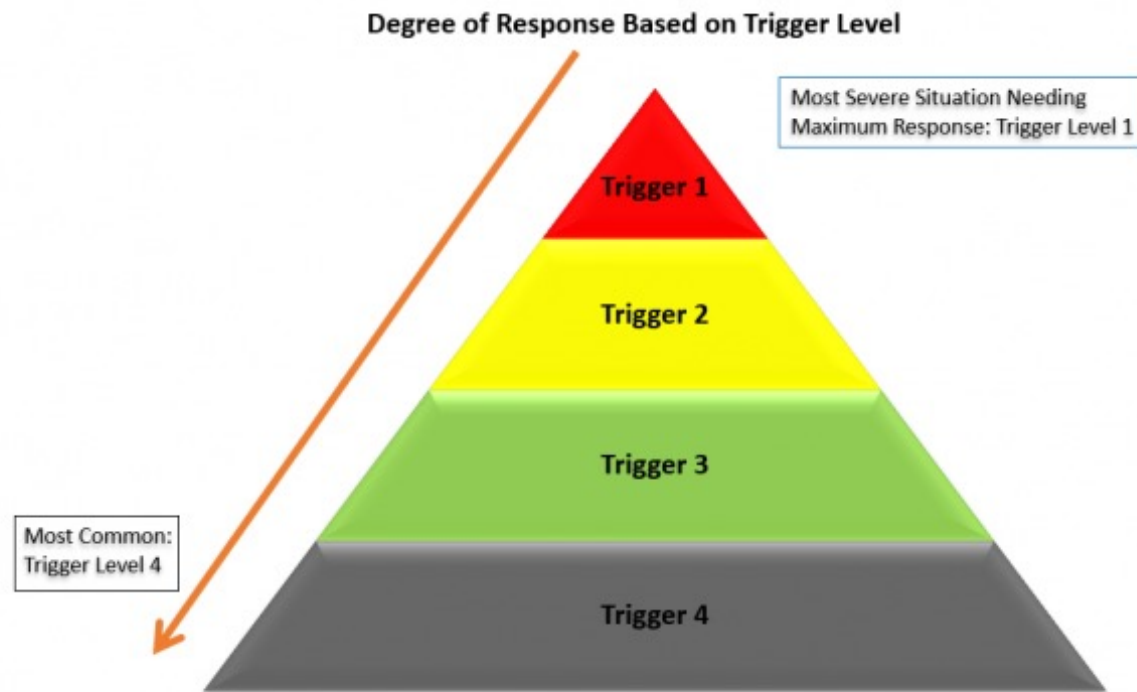
Nine Steps of Issue Response Plan

Nine Steps of Issue Response Plan



Determine Trigger Level Maximum, Proactive and Moderate and Monitor

Determine Trigger Level



Example Scenario Planning: Trigger Level 1

TRIGGER LEVEL 1: MAXIMUM RESPONSE	
Category	Issue
Patients	• Patient Death
	• Severe adverse reaction
	• Medication error
Regulatory Rulings - FDA and Worldwide Approvals	• Product recall re: safety
	• Warning letter (e.g. FDA Inspection)
	• Black box warning
	• Non-approvable letter
Manufacturing	• Contamination issues
	• Supply shortage (short term and prolonged)
	• Shipping accident
Partner Issue	• Company experiences an issue (e.g. financial crisis, BOD issues, pipeline problems, etc.)
Pricing	• Price does not reflect perceived “significant” discount
	• High cost of treatment



Issues Management Check List

- ☐ Issue is verified and situation analysis brief developed
- ☐ Trigger level and Issues Management Team (IMT) determined
- ☐ Material development needs determined and assigned to appropriate team members
- ☐ Spokespeople determined and briefed on issue/response plan
- ☐ Internal and external communications issued in appropriate timeframe
- ☐ All materials developed and routed through IMT for review
- ☐ All materials granted final RC and legal approval
- ☐ External materials distributed through appropriate channels
- ☐ Situation is monitored and appropriate follow up is conducted



Case Study 1: Balancing Act Between Large, Multi-Nationals and Emerging, Growth Companies

Situation Analysis

- Major disease category with huge unmet need
- History of clinical failures with various company's approaches not validated
- Large company X (large cap public) in-licensed company Y (small cap public) product in development with study failure
- Large company X has responsibility to communicate all data in peer review forum (not meaningful or material to them) while small company Y has little control of the message and has an obligation to share information with shareholders due to materiality
- Impacts research in entire field, something both companies are concerned about



Case Study 1: Balancing Act Between Large, Multi-Nationals and Emerging, Growth Co's

Action Plan:

- Follow 9 trigger points: this is a Trigger 1/2
- Small company Y comes together with large company X to discuss approach to communication and impact on each company and respective reputations, shareholder value and field
- Share respective communications plans and approaches to communication
 - Large company X prepares Q&A and reactive statements (no spokesperson)
 - Small company Y prepares its own Q&A and reactive statements while advising legal counsel on materiality, hence a public disclosure (press release, 8K would need to be filed)
 - Negotiation on both sides on risk management, materiality and bias/company view
 - Media outreach to key friendly reporters
 - Advocacy outreach to patient organizations
 - Media and social media monitoring; share with respective partner on day of news
 - Check point meetings to discuss impact and adjust accordingly



Case Study 2: Issues Management Proactive Planning on New Product Entrant

Situation Analysis

- Company X is developing a new product entrant in a multi-billion market for which there is a product used off-label
- Company X will do development and regulatory work in order to file for commercial use of product in category
- Hence, Company X's product would be the first approved product based on the same base drug to gain approval in this category



NOTE: For Internal Use Only
Needs Compliance Review

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Case Study 2: Issues Management Proactive Planning on New Product Entrant

Action Plan:

- Identify and develop content on the key issues, audiences and arguments
 - Pricing, reimbursement, reliance on partners, perception
- Monitor competitive intelligence
- Holding statements written in advance
- Confirm and agree on media relations and stakeholder communications goals
- Establish communications channels and plan

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Issues, Audiences, Arguments

XXX is simply creating a more expensive version of repackaged XXX

Audiences: KOLs/HCPs/Retinal societies; Compounding pharmacists; Payors; Patients/Families/Advocacy groups

Argument: XXX gives HCPs another on-label choice providing patients with safe, effective retina therapy at an affordable price; ONS-5010 is a viable treatment option across the spectrum of ophthalmic drugs for wAMD, DME and BRVO; Affordable price expands global access to care for retinal disease; Safety, efficacy, cGMP, approved labeling, unit-dose, pre-filled syringes, consistent potency, consistent supply

CMS could set reimbursement relative to repackaged XXX

Audiences: KOLs/HCPs/Societies; Payors; Regulators; Business Partners

Argument: FDA, CMS encourage HCPs to use on-label medications; FDA policy is that when an approved medication exists, compounders should not conduct large-batch manufacturing to compete; Compounding is appropriate for individual scripts for patients when no commercially available drug is available. Outlook does not believe reimbursement for its novel formulation of bevacizumab will be set relative to repackaged bevacizumab (Avastin®).

NOTE: For Internal Use Only. Needs Compliance Review

Wrap Up Conclusions

- Proactive issues management preparation is smart and ensures you have a baseline in a trigger 1 or 2 issue
- Allows for ease of handling lower trigger issues
- Being prepared helps to align management and internal team members
- Trigger 1 or 2 issues requires all hands-on deck and careful thinking and execution on the plan
- Monitoring and reporting as well as check point meetings help along the way to adjust the plan and consider what's working and what is not



Measurement Is Not Easy: How Do We Tell If Its Working?

- Monitoring and environment scanning
 - Competitive Intelligence
 - Political environmental
 - Analyst reporting and stock reaction (price and volume)
 - Media monitoring and sentiment
 - Influencer posts
- Adjust messaging based on recapping activities and feedback
- Retool story accordingly



Thank you!

Donna L. LaVoie

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Public Affairs Council Workshop on:

Issue Management

An Integrated Advocacy Approach

April 2021

Robert's Content

Part I

Current Environment

- Political Outlook
- The Actionable Knowns
- The Age of “Process Activism”

Part II

Approach & Sustaining IM

- Integrated Advocacy for modern Issue Management
- Case Study
- Sustaining Success

Part III

Value & Measurement

- Define your “Product”
- Measure Progress over Performance
- The Dashboard Approach to Measurement

Part I. Current Environment

Black Swans > Unified Govn't

2000 – 2001

The Ownership Society

Senate (Tie)

House (R)

White House (R)

2008 – 2009

Cap & Trade / Climate

Senate (D)

House (D)

White House (D)

Actionable Knowns

With unknowns abundant.

- Transformational changes likely to be driven by black swan events, with incremental change elsewhere.
- Divided electorate and political realignment make mandates aspirational.

Focus on the known.

We can plan for and act on your most important corporate or industry priorities, as well as macro trends.



The Knowns

Be proactive in an era of undefined priorities.

Expect a crowded landscape in 2021. In 2008, business advocacy groups increased spending 47%; lobbying increased 14%

Have a reason for austerity. Companies that make strategic investments in marketing and public affairs, outperform companies that don't



The Knowns

Audit and adapt for existing macro trends facing policy development.

Institutional trust remains at all time lows.

Control is increasingly distributed, with:

- Events, not leadership calendars, driving discussions (AOC Tweets)
- Exec or Admin action leading legislative policy movement, where it exists at all
- Greater public aptitude for self-organization

Lobbying now the least effective method of influence.



The Forecast in Short

Cloudy with a Chance of Populism: policy debates have been erased by an age of populism and “Process Activism”.



Part II. Approaches to Issue Management

The Approach

In an environment of distributed power, how should my advocacy approach for prioritizing, managing, and responding to issues change?

Sustaining It

With resources constrained and outcomes unclear, how do I plan for and stay ahead of issue evolution?

MOBILIZATION

Short-term

Quantity over Quality

Driven by your priorities

MAIN STRATEGY



**HIGH VOLUME OF
CALLS & EMAILS:**
Decision-makers are blanketed
by canned communications

ADVOCATE STRATEGY



QUANTITY OVER QUALITY



Evolution of Policy Making



Process over Policy

The terms of debates are increasingly likely to be set by process (Agency, Permits, Courts) over policy. This is the era of “Process Activism”.



More Pieces in Play

The bigger the issue, the less likely Washington is to be the source for the solution for the foreseeable future. States, agencies, and other non-traditional pathways are key.



Bipartisan Momentum

With even unified government unable to advance key issues, your approach must include pressure on both sides of the aisle. **This is not the same as bipartisanship.**



Integrated Advocacy

Authentic, genuine movements around an issue are most likely to impact process and policy (vs. direct lobbying or institutions).

INTEGRATED ADVOCACY

Long-term

Quality over Quantity

Advocate Empowerment

Cross-Functional
(P&GA, Brand, Philanthropy,
Independent Validators)

MAIN STRATEGY



EDUCATION & ENGAGEMENT:

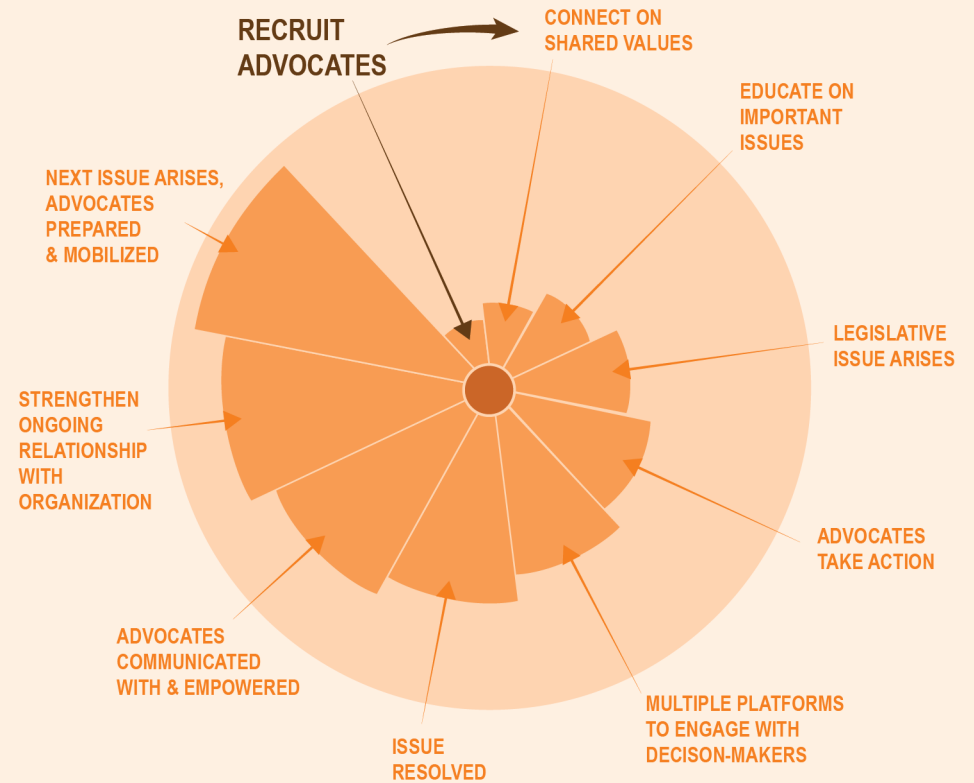
Advocates gain ownership of issues on multiple fronts

ADVOCATE STRATEGY



ADVOCATE EMPOWERMENT:

Advocates are people, not numbers in a database



Environmental Movement & NGO's

Keystone Pipeline, EPA Permitting,
OSHA, Methane

Investors, tribal nations, churches,
mom-blogs, celebrities

Communicate local impacts,
humanize effects, mobilize corporate
citizenship

Integrated Advocacy



Process as a policy
tool



Engaging New Allies



Aligning for Action

Energy Industry & Allies

Pro-active regulatory stance, selective
preemption, increased academic
funding

Labor, ag, landowners, academics,
subject matter & governance experts

Communicate local benefits,
connect energy with outcomes,
mobilize independent validators

Sustaining Success

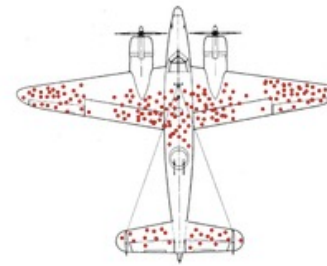
**Know your elasticity
for success.**

Would this be nice to win? Or is it
existential?

Budget (and advocate) accordingly.

Sustaining Success

Avoid survivorship bias.



Don't get lost in victories.

Continue to update research, assumptions, and processes to avoid focusing on an incomplete view of your risks.

Sustaining Success

Plan & Act

Do you have a plan to:

- Listen and respond to the communities you impact?
- Ensure you're solving the right problem and communicating effectively?
- Know if you're being heard / if you have the brand strength to be heard?

Do you have the resources & relationships to act?

Part III. Value and Measurement

Define your product.

Integrated advocacy is a process that generates an end product – brand strength, hedged risk, strategic partnerships, etc.

Products are profit centers (or loss leaders) essential to a business or industry's competitive position.

Value and Measurement

**Measure progress,
over performance.**

Where performance is a measure of the efficiency of movement, progress measures movement in the direction of a destination.

Complex issues require sustained navigation of many variables to reach a destination.

Be careful to value, evaluate, and communicate progress, independently of key performance indicators or intermediate ROI.

Measurement and Value

**Know your progress
dashboard.**

Identify the waypoints, measures, and gauges you'll watch on your "**dashboard**". What readings do you expect for a successful journey?

Communicate these readings regularly. Measure them often. And hold your navigators accountable.

Contact

About Me



Howdy! I'm a politico by passion and a Midwesterner by birth, which leaves me splitting my time between Chicago and D.C. Thanks for joining today!

My Company

Specializing in complex industry perception and regulatory challenges, I have preserved over \$8 billion in at-risk economic investment for clients over my career.

YIMBY was founded to put that experience to work on the niche area of public acceptance and values-based messaging. When the stakes are high and true expertise is rare, we assist clients as expert auditors able to improve public affairs spending and outcomes.

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YIMBY Public Affairs



Targeting and Asset Mapping

WHO DO YOU NEED TO INFLUENCE:

WHAT DO THEY CARE ABOUT:

WHAT MESSAGE WILL PERSUADE THEM:

THE ADVOCACY BOX

Who influences them on the grassstops, grassroots, on the left and on the right?

