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everybody it is my pleasure to welcome you to uh the next episode of our uh

treats talks the translational research ethics applied topics talks these are offered to you from the center for

bioethics at IU bioethics and participant advocacy program of the

Indiana CTSI and in these talks we try to cover topics that researchers are

probably confronting and may have even asked us for help with and this is a talk which actually um an earlier

version of it Dr. Madeira gave a couple years ago about advocacy and research and how to balance those two roles and

we thought it was time to revisit this and have Professor Madeira give us her updates and her thoughts as it

relates to Topics in the news right now since her last talk we've had covid and we've had the abortion debate uh in its

new form after Dobbs and so I'm really excited to hear what uh Professor Madeira

has to say and I just received her slides which is perfect then so I will share my screen and without further Ado

let me hand it over to Dr. Madeira while I fumble here for a second she's had it

off the fumbling from her to me so I get to fumble instead of her but I'm almost done is my screen being shared yes it is

and then there's the slideshow bingo will you tell me uh Jody when you want

me to Advance I'm going to mute myself and probably go

off camera but I'll be here if you need me okay so uh thank you all for having me today

and as I as Dr Schwartz said I'll be doing a presentation on how we as

researchers and as scientists can also Advocate and um here is where I'm coming from In This research although I'm a law

professor I also have my PhD in communicative studies I research how

I'll affects people's lives and I've done diverse issues such as how and

where do people experience closure following execution and murder how does terrorism affect the

populations in a city uh around a particular area in which the terrorism occurs

um how do fertility patients use emotion to make

decisions as particularly in relationships with caregivers and most recently I've been researching what's

called fertility fraud which is the interesting issue of what happens when

doctors use their own sperm to inseminate patients without their knowledge or consent in the 1970s they

told their patients that in fact they would get sperm from a medical resident resembling the husband or they would use

the husband's sperm and unfortunately that did not happen and individuals

found out later with direct to Consumer genetic testing that their parents fertility doctor was actually their

their biological father as well um and so I've passed

helped past or helped a pass about 10 state laws uh related to this in um

California had one before I've worked most directly in Indiana Texas Colorado Florida Arizona Kentucky we passed Ohio

at 3 30 a.m this morning and uh these bills generally expand uh who can sue

for fertility fraud for example uh the children born from these procedures as well as the couples that underwent

fertility treatment and they provide for both a civil and criminal cause of action in some states they state that

this conduct is sexual assault um and we also have a federal bill which is uh HR 140 1806 which is due to go up

in January at the end of January and so we feel that it's important to

pass these laws both to allow people to Sue and seek accountability from Physicians and to put this on the map in

terms of you know how law regulates technology um and there are several other

technological issues that fall through gaps um but I thought this was a good example of doing uh research and doing advocacy

at the same time I came into this issue actually

um in about 2019 because I was asked after uh the prosecution of a doctor in

Indianapolis named Dr. Donald Klein to help them pass a state law the victims pass a state law in Indiana

um and that was the first state that uh was that passed the fertility fraud law in the country

um I worked with victims to do this and in the process of doing advocacy I actually started to do research so it's

kind of backwards in in that situation um I continue to do both advocacy and

research they run side by side um and I do similar uh projects with respect to firearms and second amendment

and also abortion uh but fertility fraud is the easiest one for me to talk about I've been very deeply uh steeped

in it uh since 2017. so I think we can advance

so why would we Advocate um sometimes our field of inquiry

actually implies an advocacy position for example we might be conservation biologists we might be in medicine

um and there is this yeah this assumption that certain professions uh

explicitly medical professions are calling upon their members to become advocates for example pediatricians have

become very instrumental in the fight against gun violence and uh proponents of safe storage telling patients for

example how to safely store firearms uh we might do research um from the

get-go you might choose a project to affect a particular change in the world or we might find that our research

conclusions from certain projects support or oppose policy outcomes some call this uh action research

and this does run counter to what science traditionally is what uh you

know neutrality traditionally is what objectivity traditionally is but especially since Society has become very

divisive over social issues in particular we're actually confronted by

a tension we're asked to be both responsive to social concerns uh as researchers or social risks as

researchers you know if we're not our work is uh irrelevant uh we might not qualify for funding but we're also asked

to retain the authority of objective value-free and rigorous uh scientists or professionals and so we're becoming

increasingly aware as well that disciplines are embedded within external pressures uh their social pressures

funding priorities policy interventions and increasingly professors are becoming

known as public intellectuals as well meanwhile science is still thought of by

the public and sometimes even by practitioners as this kind of objective cold non-partisan value neutral

Enterprise and uh whereas advocacy of course is of

this very subjective warm passionate um Enterprise and so there's often a belief

that scientists do facts and Advocates do values but

um there's also been um tension in the past between the non-scientists ability to access information

um and for example to become part of this debate uh on a reasonably informed basis either this information was not

made publicly available or it was thought not to be understandable to lay individuals but now there's a drive to

open access Publications lay science literacy is increasing as early research

movements and the lines between research and advocacy are blurring

so I think we're ready to advance so when we're thinking about advocacy we

think about four key questions what do we want to change how do we want to change it what assets do we have in

order to create change and what obstacles might there be to hinder our ability to create change

and some examples of this you know the problem might come from our research it might be a social problem it might be a

problem that attracts funding and we're going to have to choose a particular uh

goal we want is it we're is it a research study that's going to give us more information about potential

Solutions is it uh packaging our conclusions in order to affect

legislation or to pass a law pass a policy um change policies change the

conversation what assets do we have to create change well that could obviously be our

research that could be our position our credentials that could be our institution um it also could be our ties with

Community organizations or our knowledge of how things work in a particular field um it could be our ability of our

research to attract money not only funding dollars but also Community dollars uh to work with non-profits etc.

what obstacles are there to hinder change well sometimes we are our own obstacle sometimes we are just sort of

stuck in this mentality where we see ourselves as within the uh academic field and we it's very difficult for us

to step outside of ourselves and become advocates other times um an issue might be very political and

we might be afraid uh for accusations of bias for example

um the easiest issues are ones where few people can disagree that there's a

problem and things need to change and so for example fertility fraud is sort of an ideal issue from that standpoint

because no one thinks that doctors should ever defraud patients and it's very easy to argue that these doctors

should be held accountable and measures put in place so that this does not happen again next slide

so again just digging a little deeper into some of these questions how do you

want to affect change we might want to stop or start a particular policy we might want to have our research

recommendations accepted we might want to change or facilitate public knowledge or we just might want to get an issue on

the agenda in the first place that was really the case with fertility fraud because no one had ever heard of it and

we've gotten to the point where you know almost the world has heard of it now through either state laws or through

mechanisms such as the Netflix documentary our father in which I was the legal expert

um next slide in terms of assets to create change this

might be again research data there might be uh relevance so relevance is an asset

um certain things whether it's from crises uh for example all of these vaccine Scholars um that I knew rejoiced

because they got to do uh vaccine studies that were relevant or explain to

politicians how to increase public uptake of vaccines when the vaccination

question became more relevant through covid-19 maybe there's a new Solution on the horizon there's sudden support from

opinion leaders or policy makers around an issue sometimes this is a temporal matter you know a legislative session

for example and sometimes there's just money out there that somebody's throwing out a problem in order to solve it next

slide in terms of obstacles um again it might be strong opponents

value conflicts lack of public support or knowledge and just lack of access to policy making and

all of these things we're going to talk about how to overcome them next slide

so in terms of digging a little deeper and beginning to map an advocacy project we're going to run into five key needs

the first is gauging a perceived need or interest for Action uh the second is

understanding who the actor stakeholders and action centers uh surrounding an

issue might be understanding current perspectives and positions how decisions are made is also a key thing to

understand and just the importance of getting timing right and again uh to insert or advocacy insert our research

at the correct time next slide so in terms of gauging perceived need or

interest questions that are relevant are is this issue on somebody's agenda who is talking about it or is this something

that we're going to have to say here's a problem and here's why this is a problem it's easier if there's interest in

momentum behind an issue is someone acting on it uh is there another group out there

um who is doing something that you do not think is sound that you're opposing um and

I think a couple are um copied and pasted twice so next slide

okay another key issue is mapping actors stakeholders in what I call Action

centers or Community organizations or institutions that might be very key to

advocacy for a particular issue so who are the main stakeholders uh who makes decisions

um who influences the decision makers where do these things happen

um or do they happen for example in a combination of community organization uh is this

something that happens in Academia is it something that happens in the legislative body and What mechanisms

right is it for speeches are there particular bills that are introduced so there are policies that are floated how

public are these materials and in what networks are these individuals organizations and processes embedded

next slide so in terms of understanding current

perspectives and positions this is really the values and interest question this might involve

um staking out the level of consensus or conflict on target issues and uh for

example maybe there's conflict over whether an issue is important at all maybe it's Salient just for a particular

group um why are these interests and values at stake what is what do others stand to

lose or gain for example money opportunity access power and how do you fit within this landscape are you

getting money to research a particular issue do you have particular kinds of power or access

um do you have particular kinds of knowledge and it might be that you're coming from a position where you have

none of these things you don't have money opportunity access or power and we're going to talk about the importance

of research alliances or Community engaged research for example to overcome these lacks next

slide we have to understand the decision-making process in great detail

um so there might be forums that look like they're the decision-making forum for example

um legislative hearings but maybe the decisions are really made through

informal processes that are not accessible to the public or to us even as researchers

and again we have to evaluate our own access and understanding of these processes as well next slide

getting the timing rate is uh really a key element it's essential why would we want

for example to get involved in the legislative process when the legislature doesn't meet uh for months and we

need to solve a problem right now so we need to change our advocacy strategy so what is the timing of key decision

making processes um maybe it's around an election cycle again a legislative session crises maybe

there's been new developments um in in technology and so uh there's

there's regulatory uh movement going on what stages are need needed to get

um a proposal or information into the decision-making process so for example for legislative sessions you really need

to start uh the summer before the legislative session starts in January and at the latest by October unless

something is really current and uh crops up in between uh very close to the start

of the legislative session you have to look how long you have to affect change and how ready will you be to take

advantage of the opening in other words this is very important to placing ourselves

um on a spectrum where we can accomplish a great deal if we have a lot of time obviously or if we have things ready to

go but we might wanted to use very specific Niche goals if we really don't have that much time we really have to

strike quickly next slide

so when we look at three issues in particular again the first of which is

mapping current thinking I'd like to dig a little bit deeper on this issue so how

do stakeholders Define the problem how is the problem or discussion framed is it frame is a political issue a health

care issue human rights etc. um what language is commonly used and this is really if you if you listen to

policyholders um policy makers stakeholders etc. um when do they talk about this in what

terms um and are those terms that are similar to your research can you make use of

that what Solutions are discussed how have actors come to understand or

derived thinking on an issue perhaps interest groups are lobbying perhaps um they're reading information in the

newspaper and how can you frame your contribution Within These factors how can you be a source from which people

derive current thinking how can you pose Solutions how can you perhaps change the language by which people

refer to an issue how can you contribute to how the problem or discussion is framed or change it how can you become a

stakeholder that helps to define the problem next slide

one of these uh another issue basically is digging deeper in mapping decision

making and this really is more of a strategy question when you go to figure

out um which we'll talk about in a moment what you're going to do how you're going

to do it um who's going to be more easily convinced by what arguments are there particular legislators you need to

Target are there particular Community leaders you need to Target are there opinion leaders that are so essential to

the issue that you need to get them on board um how entrenched are actors in uh their

current positions is this an issue that they're malleable um are other factors again values or

interests such as religion um such as demographics um are those affecting how actors

respond to a particular issue an example of this uh which we've seen over and over again is abortion right

um so actors tend to be very entrenched in their current positions if they are conservative

um if they are religious how can actors be moved is it going to take Visual Evidence visual depictions

of Statistics is it going to be uh anecdotes well you have to appear give a

presentation or bring uh perhaps a victim or someone affected by the issue to the actor who can change uh policy

and how achievable are different advocacy objectives you know sort of in this in this culture of decision making

next slide okay so before we go in and talk more about

um the actual strategy uh or advocacy itself there are some very important preliminary questions the first is are

we going to go in alone or as part of a team if so is the team relationship going to

be public is this sort of a research Alliance that you're going to announce or are individuals just going to

coordinate um sort of independently of each other

um is this going to be a an issue where it's useful to partner with organizations uh one of the best

strategies we found for example uh in state law and passing fertility fraud laws uh we Ally with an organization

that already has um certain resources which we lack or which we might lack of for example

lobbyist services and so uh when we passed the fertility fraud law in Ohio recently we went in with uh an adoption

organization actually um do we have diverse capacities and

resources and again that's another reason to work as part of a team because everybody can bring something different

to the table what roles will the members of the team fill one good potential uh

partnership might be members of an existing research team are there Community coalitions we can

build often these uh the team building is a long-term project it's very rare

that a sort of Team coalesces around an issue and you can uh Jump Right In next slide

another very important goal at the outside outset is just realizing the various

stages to influence so the first is that the audience will recognize and understand your ideas evidence and

options the second is that the audience starts to become interested and get engaged the

third is that audience the audience becomes convinced uh fourth they will make their ideas their own literally

this happens in legislation as legislative allies of yours take your idea put it into a bill and sponsor it

literally um you know making it their bill on the floor and the finally the last stage is

that they act on proposals they imp they agree to a solution they implement the solution

um that's the ultimate um stage of success next slide

um another key thing that's very interesting and important to keep in mind academics have a very fundamental world

uh view difference uh from policy makers so academics might be theoretical objective and Universal

um they question the fundamentals of policy they often lack knowledge of practical constraints uh and they may

talk in terms that are not easy to understand policy makers on the other hand are very practical political and

context driven they're resistant to change they might just go with what

works even if it's not the best solution they're driven by budget and capacity and cycles and they talk in this sort of

bureaucratic budgetary language often particularly uh legislators next slide

so when it actually comes time to deriving advocacy activities we want to

make it clear that we're not going to be focused on recounting our research conclusions but on how best to engage

audiences we want in other words to get our research to audiences through dialogue

we have to be persistent and consistent in our messaging and might be for months or years we need to have both quick

syntheses of key points and deep dives into areas of Interest we need to

have a mix of carrots and sticks for our audiences incentives to pay attention what will happen if there's no action on

an issue and um I I think we have to research represent our research conclusions uh

fairly neutrally without stretching or overreaching

so uh yes thank you um with audience values and priorities

differing we might look at a variety of events um importantly these are going to be both within and outside organizations

uh for example the organization in which we're trying to affect change whether it be an industry or a legislature and

outside through the media papers or articles briefings presentations media

events often these uh these activities are sequenced in stages for example we

make publish an article to lay the foundation and then bring or translate that to the public into policy makers

through websites and talks um often I think of this as doing waves of advocacy like the first wave might be

publication of an article the second might be you know taking that and making sure it gets before some key policy

makers that kind of thing next slide

um note that the effective advocacy uh project begins during the research

process itself or often begins uh it's great if you have this in mind at the outset to involve policy makers in

research to get feedback on design uh even analysis um because again there

might be things since you're not part of that Community which they can help you interpret um you can design research questions

that will be relevant to that Community easy to translate into policy this builds legitimacy and relevancy it

starts dialogue and it encourages these policy makers and stakeholders to take ownership in the research process

next slide now of course there are risks in

engagement there is the risk that opponents will react negatively it might affect your reputation in the uh in the

academy um there is a risk that your messages will be skewed or taken out of context used for political gain there might be

political consequences and um there's you know unfortunately one very

important thing I'm thinking of here which is uh in the abortion context you know attorney general Rokita going after

Dr Caitlin Bernard uh in uh for uh allegations that she actually betrayed

HIPAA principles or uh that she breached confidentiality and so there might be uh

an opponent out there of yours that is so opposed in in

uh practice and in principle to what you stand for um and again that abortion issue is

Central to this conversation that they that individual is going to

try to go after you on a personal level or use their office uh to sort of

exploit um weaknesses that you may have um and so it can get actually very

unpleasant um there might be irrational responses out there people may ask you to defend

your research or challenge your credibility uh so it's very important to anticipate opposition and strategically

plan responses to that next slide

again there are a few other risks

um most of which I talked about on the previous slide legal action professional disciplinary consequences

um opposition from political sources etc. next slide

and so um here are some tips just to round out the talk for engaging as advocates know that it's not just

talking but it's also listening uh acknowledge that we have both a citizen

hat that we wear and a researcher or a scientist hat and we have to be clear which one is on in given moments it's

very important to have realistic expectations or else we tend to burn out as advocates it's important to pick

audiences carefully and think about how those audiences are related to different

from similar to other audiences um it's important to know what your audience expects or can be expected to

understand for example uh it's really not the thing to bring your research article to a public gathering and hand

it out it's going to be much easier to translate those in the form of a few you

know boiled down points uh that an audience can understand and from which they can move on and discuss uh what's

important there is a boundary between scientific issues and value judgments to which we

need to be sensitive as advocates and we have to know our limits maybe we're very

uh very good at certain things not good at others very comfortable with certain

contexts not with others and I think here uh staying within our limits and again partnering with others who do we

do not feel who can do what we either cannot access or do not feel comfortable with might be the best strategy

um slide again uh how we frame issues is very

important metaphors analogies anecdotes uh translating this message into

different forms uh the sound bite that's 30 seconds the uh two to three minute

testimony the longer public uh address or a lecture

building uh trust and being transparent are also important and again that just

involves uh not overstating research conclusions being honest and and being upfront too about your credentials and

in the limits of your expertise and I believe that that is the last

slide so with that we can turn to discussion

thanks Jody that was just great um really appreciate that in so many ways um

people should just go ahead and uh put the hand up with their with their reaction and I'll I'll call on them or

Jody you're welcome to do it um I I should say I'll just start out just because I don't see any hands yet

but just to give people the time to start I I'm expecting at least these talks generally are supposed to be 30 minutes so Bingo first of all and

secondly I suspect we can fill up the rest of the time we'll take as much time as we need for the rest of the hour as needed

um to talk about experiences and thoughts about this because you laid out a beautiful uh primer I'm going to call

it of how to be an advocate in science I wondered if just to reflect on the points you made we talked about dangers

and those were very well taken I think they're very real um but I also wanted whether you would think about

as a researcher who's doing something which starts to feel like advocacy when is it unethical like when are

those where are those guide rails we should be thinking of as we're stepping over the line maybe where we're not just

worried about practical dangers or political or say funding which is of course a concern in medical research

especially perhaps but everything but also like when are we doing what are we doing when are we making a mistake when

when have we what sort of mistakes might we make where on reflection just about our own work we might consider our

work to be um unethical certainly I think if we violate

um bioethics if we violate um accepted ethical Norms if we coerce

subjects if we contrive results I think that's obviously the glaring answer

um I think to me that otherwise this is very much a gut question because we have personal ethics and professional ethics

uh of course as a researcher for example and a lawyer I cannot file

a frivolous lawsuit to see people's reactions when a lawsuit is filed so I may breach professional Norms that is

obviously unethical um but also I could violate something that I

hold to be sacred um for example if I gain access to a

particular policy maker or opinion leader by misrepresenting my stance or misrepresenting who I am why I am there

I think that starts to feel pretty icky um one of my ethical lines in fertility

fraud um basically is in uh how I will conduct

research and advocacy I um and this is actually a really good a

really good question because uh one ethical violation might be um

choosing a research or advocacy goal that is too broad if that makes sense so

if I list as my goal in fertility fraud advocacy

to help victims hold doctors accountable right then I am prioritizing helping

them bring lawsuits helping them talk to the media um but if I choose holding perpetrators

accountable and getting individuals to recognize the harms that they did as harms that's going to listen that's

going to list a different set of priorities for me an example is when you know I was passing these state laws

trying to expand opportunities for victims to soon obtain accountability and then I was contacted by an insurance

company who uh who represented one of these positions for malpractice purposes

and they wanted to retain me as a consultant to explain why what the

doctor did was wrong I was happy to to do that because that furthered my objective of communicating to the public

and to policy makers why fertility fraud was a violation but I did that at the

expense of costing victims damages because they could have sued the doctor

and the insurance would have paid the judgment uh if the insurance company was wrong so I had to make a choice between

my goal and between actually helping victims get money

answer I I love your answer I love that in this modern day where we're

relativists about so many things that if you follow the what you're going to call I guess the principles of science you

know of doing good careful scientific research then you're well immunized from

being away sad against the charity you're being ethical even though you are motivated perhaps by a certain

perspective on political or social issues hi thank you I enjoyed that

um my question so you had mentioned um well so anyway my question is

thinking about people who are maybe not a part of the communities that they're advocating for

um I'm wondering because it is a it's a huge skill set and not all of us have it and you know like some of us are maybe

currently trying to build that um those capacities but don't have them yet I was

wondering if you could talk at all about how you know when to step back when you're not the person to be the advocate

um what your role could be then to still be supportive but not to be like the face of a movement

that's a great question and I think it's important to know our preferences our strengths and weaknesses even before uh

we get involved in a particular advocacy project so some of us are comfortable talking to the media others are not

um some are comfortable with longer presentations in front of professionals others really like Community engagement

so for those who are not the face of the organization or the face of the advocacy movement they're still very

important work to be done work connecting individuals um for example

you know maybe you have uh connections that others do not or you know you're in

charge of making sure that uh everyone's on the same page before uh you go in

with your um Community Partners to give testimony um so there's that coordination or

networking effect there's um there might be technological materials to develop websites

um there might be issue papers or white papers to develop and so I think just

this the sheer scope of translation and adaptation to different audiences you know calls for a team with varying uh um

and diverse talents and capacities um it also is the case too that we're very busy around certain times of the

semester so um for example maybe your schedule is a little more a bit more flexible at

certain times uh whereas someone who has been a dedicated

um researcher a dedicated Advocate um their schedule suddenly changes so that they're swamped during the legislative

session and you can pick that up so I think it's as diverse as the research projects you might be engaged

in but there's certainly a number of roles besides just that uh front person

who's sort of the spokes the spokesperson of the of the advocacy

Kristen hi Mike my name is Kristen sorry I'm one

of the neonatologists and um my question is more sort of on the legal aspects of

things so you know as an IU employee and wanting to advocate for a certain cause

where does that put you in terms of needing approvals to be able to put

yourself out there in that role for a certain cause um or doing that without tying that to

your appointment in some way and what kind of repercussions could come of

something like that you know um it can be dicey and so just wondering

how to sort of handle that within the context of our employment yes and I think that's going to be a

question that has diverse answers depending on what position you occupy are you part of administration are you a

professor are you a researcher I mean meeting a professor who teaches and researches are you just a research

Professor a research scientist um and so there's uh no official

University policy requiring us to go for example to IU Administration and say you

know this is what I'm doing um we do have policies on the ground at IU that

suggests that for example we get approval we clear things with um the

legislative or general counsel uh I have actually never done that but um when I

testify at the legislature I always testify in my individual capacity um which is again um something we're

advised to do as members of IU um I think also what we are

doing matters um so if we're and again uh this might

be a a reflection of what position somebody is in so here in Bloomington if

a member the president let's say of the Bloomington faculty Council sends a message out to the faculty let's just go

with abortion that says um the abortion issue is affecting the student body in

certain ways right that might be taken as an Institutional message whereas if that person went to a rally or went to

testify against or for um an abortion related bill that would not be seen as quite um the level of

institutional action so I think that um that is actually one of the most

challenging and uh potentially dangerous concerns we have because we do have uh

numerous examples just this year of individuals that have politicized issues

and gone professionally after um I would say professionals employed by IU

such as Attorney General Rokita and uh Dr. Bernard and continues to pursue these

uh even when they've been cleared by the institution uh as having done nothing wrong so I think that uh if we do have

any doubt it is important to you know go through uh for example the institutional

review board talk to subject advocacy experts here at ctsi talk to the general

counsel of IU if we're really concerned um but then again uh there's always a

school of it's easier to ask forgiveness instead of permission as well and so everything we do involves risk

um particularly with some issues that are out there today

I'll comment on this too there was an email from the schools about uh getting clearance for State making statements

and um I feel always have to talk to our administration I was talking to my chair

about you know what sort of things would be considered out of line it it seems to me it's my personal opinion I'll say

what I think we should always say which is this is me as a person I hold a role here but I'm a guest I'm a host I guess

of this blog of this meeting but I will say as a person that you know I um

I if I'm very clear like you were saying during the example you gave was a person who seems to be speaking for the University and that's that must always

be clearly conveyed more than just maybe with a comment at the beginning exactly I'm speaking to you as Peter Schwartz

with uh professional experiences but um I would give speed as my as my own views and if you can make that clear I

would hope we can all speak loudly in the Public Square uh but again just like you said we are an institution we

have to negotiate with our bosses and the administration about what is appropriate and I guess you could

probably tell us a lot about the law of this if it comes down to things like um uh professional censure or perhaps uh

things affecting employment um I assume there's a whole body of law which again is an ethicist and

doctor I don't know about so we do look to you and the lawyers to help us as we explore those things initially I would

hope with conversation and understanding that there are important issues we wish to comment on and we hope we haven't

lost our freedom to do that because of our employment and I thank God that

we do not practice that we do not teach that we do not research right now in a state uh such as those that have put

restrictions on what faculty members can say on particular issues um for example

you know I as a professor could say if you need help affecting Reproductive

Rights please come see me in my office and I will help you and this is the only way I can address students is through

either an Institutional mechanism like email an Institutional uh Forum like class and I took that risk that is a

risk that others did not feel comfortable taking um and at least in one uh context there

was a professor up in Notre Dame that has faced a great deal of censure from the public

um in terms of her advocacy related uh to this issue but again the university has stepped up and said no this these

are issues of academic freedom we are supporting this professor so it's important I think to keep your institution uh informed for purposes of

support as well as you know knowing the boundaries Frank beautiful answer

right

you're on mute if you are speaking

you are still on mute

well we wait for up Frank just start talking as soon as you can up there you are you're back okay can you hear me the

dinosaur in the room I I'm 76 years old where I will be in a week or so and

I grew up in Bloomington I lived in the at 631 East 3rd which is

right next to the law school and uh Peter invited me to this via uh

the internet but I did the original work with Dr. Gary Peck at the NIH on what

became well known as Accutane and

I guess there's two questions I really have many questions but one

does and you may not know the answer does a pharmaceutical company when

they're putting forth a medication in the United States are they obliged to

give you all their information so that you make safe decisions

that's number one does anyone know the answer to that

um I think that under FDA regulations uh first of all they it depends on what's meant by you they have to turn a lot of

things over to the FDA that the public will never see but in terms of the package inserts and things uh they have

to it's pretty much the informed consent standard as I understand it uh material risks benefits side effects and

um just not uh every bit of information um but certainly uh written at an eighth

grade level certainly the minority I'm talking really about investigation

of drug brochures that they had and gave me

uh actually just one and had very minimal information in it

treated 30 human patients just not to treat them to see what the side effects were and that's all I received

then we find out that they actually use the medication in Europe and it caused

birth defects so they stopped using it now to put this in relevant terms for

you this this goes back to Dr well the first acne patient we saw was

Dr Tony Fauci's patient on infectious disease the young girl about 17 who had

the worst acne I have ever seen and he wanted us to try our medication on

her and it worked wonderfully uh the birth defect question never came up

really in real terms until uh it was out on the market

in 1982 it came out in August and you take nine to 12 months from that and

there were like between 60 and 16 000 birth defects uh recorded according in

the newspapers yes I well and

at Majors that for example non-surgical um one was Essure which was a device

that uh doctors inserted in their offices uh in Fallopian tubes into Fallopian tubes that cause scar tissue

and within you know three to six months uh it would affect infertility and of course this was wonderful for a lot of

people um and I think that um to broaden the scope of what you're

saying you know beyond the industry and the regulatory agency like the FDA

um this is where I think research and advocacy starts to cross with some of

the Lesser uh the not so appealing aspects of law so we might think that uh

for example it's important as researchers to advocate for or against a

product like Accutane or Esure if we know patients are getting hurt or if we know patients are benefited

um but then there's this whole other culture which is going on where uh personal injury lawyers get

involved they create Facebook groups and they uh start malpractice suits or start

to get claims from individuals they derive claims to the FDA uh that you know were never brought beforehand and

you know they sort of warp this advocacy process um in key ways uh for their own material

gain of course to to effectuate lawsuits um so I think we're seeing that

um quite a bit and that is an ethical issue that is a

um it's one of those obstacles I think that people have to know about when they do research uh in this field and it's

going to be a particularly difficult uh Force to counter because again uh these

lawyers have a very Financial stake very significant financial stake in those activities and it's going to be hard to

actually insert yourself and have a fair and free conversation uh for example

about a product like Accutane or Essure Peter do you have anything to add there

yeah I was gonna say Frank I'd like to do something email I know I haven't responded yet but I'm happy to respond

uh today and we have a conversation it sounds like it's important information you're bringing forth I don't know about the history of Accutane at all and we

could focus on that maybe when I go with you off offline but I do think it's an interesting issue you raised back I

assume you talk about because maybe you had access to as a researcher that would then being misrepresented or not

athlete represented in your opinion at the at the to the public I can see that being a case like you're saying it's

appropriate to bring it up here it's a matter of advocacy uh I think of you you

want to be an advocate but you have access maybe the things that maybe for legal reasons you can't disclose at

least back then Frank um do you have people come to you with this issue of advocacy Jody do you

confronted is there law there or ethics there I will say some of these questions are coming up become very complicated in

the real life very specific cases and this of course cases when you should call through the bsap program advertising yes disclosure you know call

a person like Jody who's available as a consultant you know throughout the ctsi but at Bloomington and call the

bsap program here we have lawyers too as well as ethics people to help you navigate this um but I'll I could tell

you some stories but I'll stop there um one issue that did that does come to mind that was brought to my attention uh

you know a journalist brought a device called the bridge device to my attention Bridge device was a neurostimulation

device that mounted behind the ear there are numerous issues with an article that had been published in a uh a substance

use Journal that basically um made this medical experimentation

um in addition uh Financial incentives that one of the authors had were not disclosed and this was very troubling

and the further we dug the more issues there were with the article um and I think that that was a

particularly interesting uh advocacy point because it was almost one

particular very specialized type of advocacy which is almost being a whistleblower and so if you become aware

of wrongdoing you can bring it to somebody's attention uh bring it to the journal's attention bring it to the

fda's attention bring it to uh a governing body's attention etc. go to the media

um and again it's in these contexts that it's very important to look out for your

own uh protections as well look at very carefully at the risks and the boundaries you might have and sometimes

the best way to do advocacy is anonymously as well uh

it's my hand up yeah

the thing about I did try to bring attention to to it I actually The

Washington Post sent a reporter to my office in Ohio

and it was on the first page of the Washington Post I said I think I sent

you a copy Peter and uh this is obviously bothered me for 25 to 30 years

and uh it's kind of oh has been over uh since I put this I pledge

uh program in which is very complicated for Physicians and dermatologists to use

uh the other thing I'd like to comment on is the risk

Hoffman La Rose which is a pharmaceutical company that brought out Accutane

took me to federal courts and although I won

I lost I lost emotionally I lost about four or five hundred thousand dollars uh

I mean it was you know to them that's nothing to me that was a tremendous

amount uh I couldn't even get my wife to come and sit in the back of the room

and they had 10 lawyers at a desk and I had my one lawyer who was

couldn't hardly hold a book still because he was so nervous but uh there are risks to what you do

sometimes you don't see understand them and I I kind of

push their button a little bit because I quite honestly felt that there might

be physical harm according to what was taking place at phone calls to my wife

and so forth it's a long story I was going to write a book my lawyer said you

want to go back to federal court I said no and then I kind of let it lie and

that's where I am so that I just want to I don't have really

expect an answer but I just want everyone to know there is a risk the

risk can be great and how great it is no one really knows sometimes

yes and sometimes there are risks to not doing anything too um and uh I do believe that sometimes

those individuals that step forward and Advocate or again it's particularly in The Whistleblower context they uh often

end up materially poor off um but they and that at the end of it

all might be able to live with themselves it's for every one of us to weigh those costs uh and

whether we can do that whether we're that's in our capability or not so thanks again for your comments in the

story I gotta let me let me go respond to your email I'm sorry I I haven't yet Joey can I say well you just maybe help

cap this off um I know we have only a couple minutes so I do want to end on time but you know you said something in the Middle where I kind of giggled and

kind of smiled and I was happy because you talked about how science you know is supposed to be sort of expect to be

value free and of course we've lived through now a few years where that's uh

hard to convince people of that um a certain segment of our population for sure and it's almost quaint that's

why I kind of smiled um is that still sort of a thing would you say in the advocacy world where you

are coming as a person of science bringing the facts of course a lot of us

still feel that way or is that something where now you're just sort of seen as another member of the scrum you know

with policy goals or is it someone's in between or how do you think about that when you think of advocacy and

being a researcher I think you have to maintain very uh tight lines about where

you go and what you do um and for example if I speak to the media

um there are things that I or types of things I will say types of things I absolutely would not say

um and I want to both represent my own research and my own perspectives and my

own expertise and uh but at the same time you know I have to acknowledge at points that my own personal beliefs and

values and I try to always be clear about when uh again those personal

values and beliefs are affecting or even standing in place of my research conclusions

um one of the individuals that I wanted just to recognize here who did a marvelous moment of advocacy

um during the Senate hearings on sb1 the Indiana abortion bill is Dr Mary Ott and

she got up and testified very succinctly very matter-of-factly and uh put a great

deal of passion into these um into statistics on why abortion was a

health care issue why it was necessary to protect abortion rights in the state of Indiana and I think uh her comments

Galvanize those that came after and set a very high uh floor for

um the kinds of rigorous um yet um

very human um forms of advocacy where that we can

engage in um I think that was uh certainly an example that I have used many times in

front of my classes and will continue to Bravo Mary do you wish to respond

sorry thank you um I have to say though the one thing that really was painful throughout the

whole thing is I was testifying as an Indiana Pediatrician on behalf of the

Academy of Pediatrics and I could not use my IU Health anything I wore a white

coat to identify myself as a physician and put an i stand with kids button on

top of my Riley symbol so that wouldn't be identified as part of IU so it was

um you know it was just very interesting the um the piece of it where I

really had to just divorce myself from my like professional role as an IU faculty member and it just goes to show

how many professional roles and professional hats we can wear in these efforts foreign

good stuff well we'll end um uh and again thank you Jody for the presentation I really appreciate it I

think it's really topical Atomic topic and again people who are facing these questions but I think are everywhere uh please feel free to consult with

the bsap program but bioethics and actually it has to be Pap program participant advocacy

um and we're accessible through the um web page that I think there's a link in the in the invitation and also of

course to us individually Mary is Dr. Ott is one of our faculty as am I and uh

Dr. Madeira as well as others so thank you for being here we'll have this posted online with maybe well usually put some

reading with it too on our TREATs pages and again we uh we hope to see you all again take care

thank you