

Transparency, Accountability, Unintended Consequences

Sunlight is the best disinfectant

–US Supreme Court Justice Louis Brandeis

Integrity without knowledge is weak and useless, and knowledge without integrity is dangerous and dreadful

–Samuel Johnson

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One of the most critical ingredients in any effort to develop a workable and effective process for the discussion of the various elements involving harm reduction is the assurance and commitment of all stakeholders and parties to the notion of real transparency. Several other sections of this paper will address how that ‘real’ transparency might be encouraged and take place. Here we deal primarily with some of the underlying issues, past histories and the behaviors of the stakeholders, and the legitimate and illegitimate use of the arguments of unintended consequences.

What has been occurring in the political environment, rocked by scandals, influence peddling, special interests and money, should stimulate and encourage us to step back and look at what kinds of similar problems and behaviors are occurring in the tobacco environment.

For the most part I have found that a large segment of the stakeholders and other various parties intentionally or unintentionally have not been transparent, open, or honest about their positions, their views and what drives them. They perpetuate a ‘silo’ way of thinking only looking at their own interests and failing to either understand, take into account, or even more importantly take advantage of the views and actions of others.

They often use the argument of ‘unintended consequences’ as a tool to prevent dialogue, to avoid transparency, to promote self-serving goals, and to impede progress. I can only conclude that we have a great deal of work to do in this area if there is to be real long term sustained progress in efforts to reform the tobacco industry and to reduce mortality and morbidity from tobacco use. Transparency is in many respects the lynch pin to effective harm reduction strategies and meaningful tobacco product modification. With it we can move forward. Without it, we are doomed to continue along the road we have been on for more than three decades. I think it can be done, but behaviors of all the stakeholders must shift.

The Tobacco Manufacturers

More than half a century ago, in January of 1954, in a statement to the public, the tobacco industry embarked on what would be decades of deceit and deception. [A Frank Statement to Cigarette Smokers](#) published in major newspapers proclaimed:

We accept an interest in people’s health as a basic responsibility, paramount to every other consideration in our business.

We always have and always will cooperate closely with those whose task it is to safeguard the public health.

A Tobacco Industry Research Committee was set up and the industry further assured the public that:

In charge of the research activities of the Committee will be a scientist of impeccable integrity and national repute. In addition there will be an Advisory Board of scientists disinterested in the cigarette industry. A group of distinguished men from medicine, science, and education will be invited to serve on this Board. These scientists will advise the Committee on its research activities.

In 1964 with the release of the first Surgeon General’s report and facing action by Congress, the industry went on the defensive again, arguing that there was no causal connection between cigarette smoking and disease when in fact we now know that their own scientific research had concluded as much. From 1964 and for the coming decades, the industry would concede to nothing, quick to develop legislative and

public relations strategies to ensure that no laws affecting the industry were enacted. As a former VP of the Tobacco Institute, Frederick R. Panzer was to later acknowledge in a 1972 confidential memo to TI president Horace Kornegay, the holding strategy was 'brilliantly conceived and executed' and involved:

- "creating doubt about the health charge without actually denying it."
- "advocating the public's right to smoke without actually urging them to take up the practice."
- "encouraging objective scientific research as the only way to resolve the question of health hazard."

What would also follow would be years of so-called 'voluntary approaches' to the ever-mounting public health crisis that in the end were never intended to accomplish much except to head off legislation within the Congress and to buy time, good will and to put a faux-face of corporate responsibility on the industry. What would follow would be the funding of 'front groups' that would give legitimacy to the industry's efforts without leaving 'fingerprints'. What would follow would be efforts to be seen as 'cooperating' with government and the public health community as was the case in the NCI's efforts to look at the development of a 'safer cigarette'.

Millions of pages of industry internal memoranda, faxes, and other enlightening and damning documents have become available to anyone who wishes to review them, giving us a window into the industry's operations and thinking about how it sought to protect its business interests at the expense of public health.

And let's not forget that image, worth a million words, of the CEOs of the tobacco companies standing before Congress under oath and one after the other, stating straight-faced that 'nicotine is not addictive.'

The deceptions were not just limited to the cigarette companies but also applied to the smokeless industry as well which developed similar tactics and strategies in order to head off meaningful and needed oversight and regulation of their products.

"The rest," as they say, "is history."

Had the tobacco manufacturers, individually or collectively accepted the conclusions of the Surgeon General's report(s) and taken appropriate steps as they had promised in the 1950's, millions of premature deaths might have been avoided, and the industry would have avoided the continuous litigation that today still plagues them.

Steven Parrish, today a Senior VP with Altria all but acknowledged the industry's serious shortcomings when he put it this way:

Put simply, ours was a culture of arrogance, bred by insularity and enabled by spectacular business success. Our tobacco companies evolved an approach towards important societal issues such that, if a given position was legally defensible, it was good enough for us. There was a bunker mentality, an "us-against-them" attitude, a belief that anyone who disagrees with us was an enemy out to destroy us.

This approach manifested itself in many ways and over time, had a disastrous impact on our corporate reputation. Take for example, our public position on key smoking and health issues. We focused on what was not known rather than listening as part of a meaningful dialogue. We argued over definitions rather than advancing solutions.

It seems clear in retrospect, that had our companies simply deferred to the Surgeon General's famous conclusion in 1964 that smoking causes lung cancer and not uttered a word of criticism against it, irrespective of the views of internal scientists much of the rhetoric and ill-will directed at us today would be without foundation. Perhaps even more strikingly, had they accepted the Surgeon General's revised definition of addiction in 1988 rather than argue about which definition had greater validity, that famous image of the seven CEOs raising their hands before a congressional committee would never have become ingrained in America's collective consciousness. The reservoir of public anger that has built up against us would have been deprived of one of its primary wellsprings, and there could have been a foundation for problem solving instead of continued conflict.

(Yale Journal of Health Policy, Law and Ethics, "Bridging the Divide: A Shared Interest in a Coherent National Tobacco Policy," Winter 2002, Volume III, Issue I, page 111.)

Today we have to ask, have parts of the industry really changed? Is there hard evidence of change? Do recent statements by Altria and BAT to subscribe to and adhere to corporate codes and guidelines of ethics and responsibility mean anything? Does Philip Morris' support for FDA reflect significant change warranting consideration? Or are these efforts just another sophisticated public relations ploy similar to tactics of the past? For the moment, it may be a little of both.

Can the tobacco industry be socially and corporately responsible and accountable?

Over the last several years the tobacco industry, at long last, has had to acknowledge and accept what was known and accepted for decades about the serious hazards of cigarette smoking. Now they are faced with new challenges in a world where they admit their products are hazardous.

There has been a great deal of focus on Corporate Social Responsibility (CSR) over the last several years. CSR means different things to different people. While CSR probably has roots dating back into the 19th century, its current focus seems to be on the notion that 'corporations should be required to return more to society, because of their impact on society was driven by pressures from civil rights, peace, and environmental movements, of the last half century.' (N Hirschhorn, *Corporate Social Responsibility and the Tobacco Industry: Hope or Hype?* *Tobacco Control*, 2004;13:447-453.)

In recent years the major companies have stepped up their appearances at CSR conferences and meetings — talking about their new found corporate and social responsibility which has brought a clamor of noise and concern from some of the public health community and others interested in corporate ethics and accountability. The question that has to be asked, is this the same old wolf in sheep's clothing? Is there anything really different?

Australian tobacco control expert Simon Chapman has described the industry focus on the issues of social and corporate responsibility as follows:

Faced with the Niagara (release of damaging internal documents) of embarrassing revelations, including thousands from its highest officials, the international industry changed strategy. It embarked on the world's most public rebirthing exercise, asking to henceforth be appreciated as an ethical industry devoted to providing tobacco products to sentient adults, all supposedly fully informed of the risks they took.

There is wholesale cynicism and disgust in health and medical circles about this exercise. Critics point out that contrary to the most elementary procedures for wrongdoers seeking public contrition, the industry has made no public apology about its years of misleading conduct to accompany its volte face. Doubtless mindful of the legal ramifications of doing so, it has made no admissions that it lied to smokers in the past, and that for decades engaged in a globally orchestrated campaign to falsely reassure smokers.

Given an industry that intends to remain in the cigarette business for the foreseeable future, what are tobacco control advocates to do? They must maintain the pressure for bans on public smoking, higher taxes, counter-marketing, effective regulation, improved methods of cessation, and ratification of the FCTC. Also essential is to caution the public against uncritical acceptance of the tobacco industry's mantle of 'social responsibility.'

*(S Chapman **Tobacco Control: Advocacy in Action: Extreme Corporate Makeover Interruptus: Denormalising Tobacco Industry Corporate Schmoozing**, 2004;13:445-452)*

Mitch Zeller, a former associate commissioner with the FDA and a consultant to pharmaceutical interests expressed concerns that the tobacco companies (PM) are using the issue of harm reduction as part of an effort to build corporate credibility. As the NY Sunday Times Magazine noted:

To Mitch Zeller, there is more than mere economics at work: Philip Morris's reduced-risk project fits into the company's broader campaign of corporate and social responsibility (the hundreds of millions of dollars spent on youth smoking-prevention efforts, for instance) and its cultural philanthropy. And of course it also enables the company to show judges and juries that it is taking steps

in the direction of harm reduction. "All of these programs are part of a much larger strategic effort by Philip Morris to change public perception," he says. "One of the goals here is to demonstrate to their target audience that they are a changed company, and they have achieved, – 'social alignment' and 'corporate normalcy.' Already public opinion surveys have shown that the company has significantly improved upon its abysmal public image of the late 1990's. PREPs, Zeller says, might help even more. They present an enormous opportunity for the rehabilitation of a consumer product. And the rehabilitation of a corporate reputation that seemed beneath contempt as recently as just a few years ago.

(New York Sunday Times Magazine, "A new cigarette filter may make smoking a lot less harmful. But is that a good thing? Incendiary Device," Jon Gertner, June 12, 2005, page 51.)

As noted elsewhere in this paper (and worth repeating) the tobacco industry has been a dismal failure in its attempts to provide full and complete disclosure about its products to the very people who use their products. Even if there is value to establishing and enforcing new codes of corporate responsibility and accountability I firmly believe **they should not be a substitute to the broader efforts related to tobacco control and they must be measured through action and transparency not merely words and rhetoric.** They cannot and should not be used as public relations tools to give legitimacy to the industry without clear and demonstrable results.

That said, it is also useful to sometimes step back from our myopic approach to tobacco and take a fresh look at an issue to put it into perspective. A recent commentary by Mallen Baker entitled, *Can companies that make products that kill be socially responsible?*, provides some interesting perspectives on the issue. He first points out that "killing people is wrong. That is one of the earliest principles established by any civilized society. So how can a company be considered socially responsible if its products – used as instructed – result in loss of human life?" Part of the reason says Baker is a change in the definition of what corporate responsibility is. He says that the changes are obviously creating 'a certain degree of disquiet.' "The campaigners have dismissed any claims to responsibility on the part of such companies (including but not limited to tobacco) drawing attention to the worst impacts of the use of their products. Likewise some on the CSR movement have felt

uncomfortable about their newly discovered allies, and would really wish they would go away and play their role of corporate villain with a little more conviction." Baker points out that while it is understandable to 'damn the tobacco companies', there can be some unintended consequences. He then asks a very important question. Can an industry such as the tobacco industry ever be legitimate, noting:

This is not a question that any individual company acting on its own can answer – it is the gift of a broader society to establish that something is legitimate or not. If people of the world believe that, for instance tobacco is a product that simply should not be allowed, governments can act to simply ban it. There is no doubt that if tobacco had been discovered for the first time today, it would never be allowed to go on sale if its full health consequences were revealed.

For the time being and for many reasons governments have not taken the steps to ban the product or the use of tobacco but rather to regulate it and control its use. Few public health authorities have called for a ban on tobacco. Baker then goes on:

That being the case, we then have an option on how that informed choice is met. We can have unscrupulous companies, very happy to sell as much as possible with little care to the consequences. Many would agree that such a description certainly fits some of the tobacco companies historically.

Alternatively we could see a different type of company. One that seriously invests in research to develop reduced harm products. One that manages its environmental impact carefully, and treats the people in the supply chain with respect. One that supports its own people, and which aims to improve society through a process of "giving something back."

That would surely be the definition of a socially responsible tobacco company. You might still not think that any existing company actually meets this definition. But a number of those companies are now stating that these are all things that they address or aim to address. If we agree that it is important how these companies operate, we should welcome the aim and then judge them by their actions.

The alternative is that we say that we don't care whether these companies ignore the harm caused by their product, despoil the environment and treat their suppliers and staff badly - because we think they are far beyond the pale.

*(Can companies that make products that kill be socially responsible?, Mallen Baker, **Business Respect** e-newsletter, September 2005)*

I believe that tobacco companies and those associated with tobacco companies should be corporately responsible and accountable to society. It troubles me however, that what they (BAT and PM) are doing smacks of some of the same approaches that have been used in the past—attempting to sell their legitimacy through backdoor routes by appearing in conferences and other public forums. As with much in the tobacco arena, success or failure of reforming corporations and holding them accountable will depend on what is done and what actions are taken. But we shouldn't just be concerned about the PMs and BATs of the world. In the long term we should be seeking to push for accountability standards that should be applied to the industry as a whole. Just as we need oversight of the industry under an agency like the FDA, we also need meaningful corporate accountability standards that all of the industry should operate under. Baker's points are therefore worth considering. While it is right to focus on the major, most economically powerful companies and the ones that have track records of dismal failures, it would be a mistake not to look down the road to see what might happen in an environment in which PM and BAT were no longer the dominant players. Does what they have said about corporate and social responsibility, independent of their actions, also send a potentially valuable message to the hundreds of other companies that are part of the global 'mix' of companies in or related to the tobacco business?

This raises other interesting questions and scenarios. There are a few other companies associated with the tobacco business who have begun to set or call for a different set of operating and manufacturing standards. Should such entities be routinely chastised because they are the 'low hanging fruit' or do they play an important role in helping to force change in the entire tobacco industry? Do we turn our backs on forcing accountability and change on the industry or do we push for establishing workable and measurable standards of accountability and responsibility for the entire industry? If we are in fact to have greater transparency on the sharing of data and

scientific research, we will need to have complimentary standards in place that deal with the broader issues of corporate responsibility. Corporate social responsibility is in some ways similar to the issues and goals related to 'competition.' If some companies can actually demonstrate through their actions new ways of conducting their business, such actions could force changes on the broader industry.

Star Scientific for example, an upstart company that developed curing methods and standards for significantly reducing TSNA (and to whom I provided some advise to several years ago) issued a Board approved policy statement in 2002 that included the following:

Star Scientific accepts and supports effective measures at the national, state, and local levels to ensure that tobacco products are not distributed, sold or marketed to children and adolescents.

Star Scientific acknowledges that the use of tobacco products generally pose health hazards and that no known tobacco product or process, even the process that Star has developed, while virtually eliminating nitrosamines, eliminates all health hazards associated with the smoking of tobacco.

Star Scientific supports having the Food and Drug Administration (FDA) as the lead agency charged with overseeing the implementation of fair and meaningful regulations over the manufacture, sale distribution, labeling and marketing of all tobacco-containing products.

Star Scientific supports increased biomedical and allied research by the private sector as well as such federal agencies as the FDA, NIH, CDC, and USDA that will continue to identify and understand the complexities of what causes disease associated with tobacco use and work to find ways of reducing/or eliminating these causes, and setting standards and "bench marks" for the development of reduced risk and less hazardous tobacco products.

Star Scientific believes that adults who chose to smoke and or make an adult choice regarding the use of any tobacco products should be fully and completely informed about the dangers of the tobacco products they choose to use, including specific information regarding

ingredients and constituents of tobacco and tobacco smoke and the levels of such toxic constituent elements in tobacco and tobacco smoke. This should include any scientifically established information that indicates that a product may or will reduce certain exposure to major toxic elements associated with tobacco use.

Star Scientific believes that the time has come for health groups, researchers, scientists, policy makers, senior government officials, tobacco farmers, and responsible tobacco companies to sit down and talk about the future of tobacco and the tobacco industry, including an articulation of reasonable parameters under which new products that will reduce exposure to certain toxic constituents in tobacco and tobacco smoke can be developed, evaluated and marketed.

To my knowledge, Star is the only company (PM to a limited extent) that has through an *official* Board action laid out its views on a spectrum of issues that if accepted by the entire industry could have a significant impact on reshaping the tobacco environment – giving public health the primacy that it deserves and needs. It would seem that all tobacco companies, all grower organizations, all biotech companies and others who directly or indirectly are involved in the production or manufacture of products containing tobacco and tobacco products should enact similar *board-approved* statements that will commit them towards effecting meaningful and positive change.

The Public Health Community

It has become increasingly clear in the last several years that the rapidly changing tobacco environment is also forcing the public health community to deal with issues that can no longer be seen as black or white but which have multiple shades of gray. In my more than thirty years of committed involvement, I cannot recall an environment in which there has been more divisiveness and in some cases internal hostility and personal attacks than have been seen over the last five years.

While the public health community wants to convince the outside world that there is agreement on issues the reality is that the ‘agreement’ is in many areas only skin deep. Personalities, egos, turf protection, competition for funding, and other factors are all taking an unfortunate toll.

Several highly respected tobacco control advocates and

scientists have made some recent off-the-record comments that are indicative that true open dialogue and transparency are often discouraged, and even suppressed and for which there are often retributions.

One commented, “if you dare express a different opinion, you are considered unethical.”

Another pointed out that the community has taken on a “you’re either with us or against us” philosophy.

And a third has suggested that “we in the public health community have taken on and use the very tactics that we accuse the industry of using.”

As a community, the public health community can and must do better in its efforts to accept and respect the views of others, to involve broader and more extensive disciplines and to step outside of its own tunnel-vision approach to the world. Ideas and views should be encouraged, not suppressed. One thing is for sure, there are no silver bullets and no easy solutions.

It may be useful for the entire public health community to also lay its cards on the table as to who is who and who receives funding from whom. Those who carry the water for the pharmaceutical industry or who receive funding from them should be willing to make those relationships more publicly known, especially when they serve in positions or present views that are listened to by others. The community should be willing to take a collective stand against those who attempt to suppress discussion or who resort to maligning individuals for self-serving purposes.

I also struggle with the notion that while some condemn taking any and all money from tobacco interests, some are able to justify the use of tobacco dollars because of the conditions and manner in which it has been obtained and secured. There seems to be a tendency on the part of some to ‘draw a line of convenience’ when it comes to justifying the use of the money for their goals and objectives. The formation of the American Legacy Foundation and the grants it has provided to many tobacco control advocates and scientists for some very significant and valuable work is a good example. No matter how one wants to frame it, no matter what ‘fire walls’ there are, the money still comes from the industry and there are

conditions under which that money can be used and will continue to be made available.

I would also hope that for clarity, transparency and for the sake of discussion and debate that those, whose goals it is to 'drive the industry into the sea and out of existence,' would say so publicly. It would make their involvement in many tobacco control issues (including FDA oversight) unnecessary and moot.

The notion that "we don't talk to the tobacco industry" is in fact a myth and has been for some time. There is in fact much more engagement (mostly on a one to one basis) than people are willing to accept or acknowledge. Much of it is at the national level but there many examples at the state and local level as well. The time may be ripe for 'sunlight to shine' on these efforts and to acknowledge that carefully managed 'engagement' between parties is both necessary and inevitable.

The Pharmaceutical Industry

While the tobacco industry (and related industries) obviously is and remains the primary focus in the discussion in the development of harm reduction products, the pharmaceutical industry must be considered in the scheme of discussions relating to the development and marketing of harm reduction products. They are an increasingly influential corporate power in the tobacco control arena and are a corporate competitor to the tobacco companies. This has not just occurred overnight but has been steadily increasing for the last ten years.

The principles of 'transparency' should extend to the pharmaceutical industry just as rigorously as they are applied to the tobacco companies. But they are not. Like any corporate interest, whether in the automobile industry, the oil industry, or the food industry, the name of the game is the maximization of corporate profits and working for the interests of the shareholders. The pharmaceutical industry, like any other corporate entity, competes amongst itself as well as other entities and uses a variety of means to position themselves to maximize sales, visibility and credibility for their products. The pharmaceutical industry is deep into the development of cessation products, both in terms of drugs as well as devices. I don't see this trend changing.

Should the standards of transparency that we demand be applied the tobacco industry also be applied in a similar fashion

to the pharmaceutical industry? Does pharmaceutical money going to the tobacco control community, NGO's and researchers have the same effects in shaping outcomes that people fear about tobacco money. Many believe they do.

As we did in the previous section it is sometimes good to step back and look at the picture from a distance.

According to the Center for Public Integrity the pharmaceutical industry," has spent more than \$800 million in federal lobbying and campaign donations at the federal and state levels in the past seven years. No other industry has spent more money to sway public policy in that period." (Drug Lobby Second to None – How the pharmaceutical industry gets its way in Washington, Special Report, [Center for Public Integrity] website, www.publicintegrity.org) The strategies and tactics employed by the industry bear a striking resemblance to the very tactics that have been used by the tobacco industry.

In addition to its heavy influence on policy makers in the Congress, another of the strategies that the pharmaceutical industry regularly employs is its effort to partner with the public health community often in the form of significant financial contributions to fund programs. This obviously extends beyond tobacco related efforts. The funding often goes to the same NGOs who are heavily invested in tobacco control. In an article entitled "Surrogates for their Agenda: How the drug industry uses non-profits to push its interests" the Center for Public Integrity notes :

Many of the pharmaceutical industry's biggest names are no strangers to the world of corporate philanthropy. They shower millions on public advocacy non-profit organizations with a variety of missions. Some groups tout the support of pharmaceutical firms. But because these non-profit organizations are under no legal obligation to reveal their donors, they provide the drug industry with another avenue through which it can surreptitiously spread its message. And while some groups that the industry funds are independent many are little more than echo chambers, designed to support positions favorable to the pharmaceutical industry that pays their bills.

The Center for Science in the Public Interest's Special Project Integrity in Science has noted:

There is strong evidence that researchers' financial ties to chemical, pharmaceutical or tobacco manufacturers directly influence their published positions in supporting the benefit or downplaying the harm of the manufacturer's product. (See www.cspinet.org)

In the tobacco environment it is not a misstatement to say that the pharmaceutical industry has spent tens of millions of dollars in its partnerships and relations with the public health community, scientists, consulting firms and public relations firms in its efforts to position themselves to tap into the cessation and risk reduction product markets. The pharmaceutical industry and its consultants can be found at every major tobacco control conference, not only making significant financial contributions but also working the crowds, helping in setting up workshops and providing conference paraphernalia emblazoned with their logos. They can be found underwriting programs at the national, state and local level. Industry consultants and personnel routinely meet, strategize, and network with the public health community. **While there is no question that much of what is being accomplished is meritorious, other issues and questions need to be asked and answered.** Their products carry endorsements of well-recognized NGOs who receive significant financial support from their pharmaceutical partners. Tobacco control has become increasingly dependent on their 'good will.'

While "no strings attached money" from the tobacco industry is rejected and criticized as tainted by most, very few concerns seem to be publicly raised when it comes to pharmaceutical money. From the standpoint of 'corporate influence', aside from the fact that the products that the pharmaceutical industry produces are obviously very different than those of the tobacco industry, I am not sure there is much of a difference. Are we again, allowing a 'line of convenience' to be drawn?

This might be changing in some sectors. In 2003 the Society for Research on Nicotine and Tobacco (SRNT) debated and discussed the issue of pharmaceutical influences on both the organization and individual research. SRNT President Harry Lando (2002-2003) noted in his outgoing remarks:

Questions were raised concerning appropriate topics and tone for listserv postings and a number of heated exchanges occurred. There was discussion of appropriate sources of funding both individuals and the society and

consideration of types of current funding and past financial support that should preclude eligibility for elected office. There were concerns raised that SRNT was too closely aligned with the pharmaceutical industry.

The issue(s) caused such a stir that SRNT developed a policy statement entitled "Declaration of Interest" noting that:

The science of nicotine and tobacco research, as does all science, needs to be beyond reproach. The presence of undeclared sources of support and financial interests has the possibility of undermining the credibility of published work regardless of whether the financial factors emanate from tobacco or non-tobacco industries. The issue of credibility is especially salient in the charged political environment in which this work is published.

Is the decision by some in tobacco control to aggressively push tobacco cessation (rather than nicotine cessation) partially influenced by the relationships and funds of the pharmaceutical industry? Is the backlash and split within the health community over the notion of harm reduction influenced in some way by the involvement of the pharmaceutical industry? **Real** transparency may provide some answers.

Just how much money is spent each year by the pharmaceutical industry to influence policy decisions and cultivate relations with the public health community and research institutions is unknown. It is obviously extensive. I will leave that investigation to be conducted by someone like the Center for Public Integrity. This paper is not intended to be an investigation into those issues but rather intended to point out a significant and important area where transparency is needed, and where it seems that a 'double standard' exists and has the potential to get worse.

Policy Makers

As I put the outline of this paper together, I did not initially include policy makers or governmental agencies in this section. But as I was writing it, it became very evident that it would be a serious omission not to consider a brief section on how our Congress, the Executive branch, and many of the independent agencies have become increasingly less and less transparent and more and more influenced by money, politics and special interests.

The recent Washington scandals involving the influences of money and corruption are really not isolated incidents but are indicative of a deeper set of concerns going to the very heart of our democratic processes and way of life. Effective democracy in fact depends on transparency and ethics and the critical need for ideas to be heard.

I would not be saying anything new or novel by suggesting that the tobacco industry (as well as the pharmaceutical industry) has a long history of influence peddling in the US Congress and in the Executive branch. The influence of Phillip Morris (Altria), RJR (Reynolds American) Lorillard, UST and several others is well known. The amount of cash that has been given to politicians is well documented and continues to this day. What is distressing is that even as there has been a growing consensus among many of the players that the time is ripe for action on tobacco policy, a few companies and special interests have the power to continue to block efforts for change.

Over the last several Congresses, in spite of the fact that there were efforts to pass FDA/tobacco legislation, no substantive hearings were heard on this issue or other important issues related to tobacco. A hearing on the tobacco buyout was clearly one of 'political expediency' forced to take place but with a predetermined outcome. What could have been a hearing to help reshape tobacco agriculture production in this country and address legitimate public health concerns was conducted in an effort to 'demonstrate' that there was no consensus when in fact there was significant consensus on the issues. Two hearings scheduled on the same day on issues related to harm reduction and tobacco product modification seemed to be more about a committee jurisdiction 'spat' than efforts to develop policy recommendations.

It would seem to me that if Congress were concerned about preventing the premature deaths of over 400,000 Americans; if Congress were concerned about reducing the billions of dollars that are spent each year on health care costs and lost productivity; if Congress were concerned about smuggling and illegal trafficking; and if Congress provided leadership in bringing parties together to craft effective and necessary legislation, it would have held hearings on the issues and moved forward with a truly workable and effective plan. But it has not. Committee Chairmen, particularly in the House, seem to be reigned in when an issue doesn't meet the views of members in the leadership. Outcomes are often predetermined with little to no

input from those impacted or affected. In the 107th Congress, one company, through its monetary contributions, influence peddling, and political maneuvering basically derailed efforts that dozens of organizations in the public health community, in the grower community and even some big players in industry had supported and had worked on for years. These lobbying efforts extended to the White House as well with the result that the White House refused to take any leadership role on the issue. Democracy and transparency were sacrificed for politics, money and greed.

Earlier, we noted the influence that powerful political interests can have in distorting and manipulating science for self-serving goals. It concerns me that the very regulatory agencies that are expected to ensure effective protection of the public's health often find their hands tied, their budgets slashed, and their voices silenced in effort to promote the goals and interests of a few.

In the decades that I have worked on the tobacco issue, the times have been few and far between when an agency like the FDA, FTC, USTR, EPA have been able to do their work on tobacco issues. They have had to fight special interests, influence peddling, and politics every step of the way.

If Congress is serious about cleaning house and reforming itself and finding workable and meaningful solutions, it must take steps to hold a series of hearings to assess what changes are needed to reform this nation's tobacco policies. It needs to be willing to listen to *legitimate* views and recommendations and move forward. Staged hearings or refusals to hold hearings, and behind the scenes decision making must be ended and democratic systems restored to the Committee system and to our representative government.

Restoring the public trust and transparency in our democratic institutions is urgently needed.

Unintended Consequences

Before making any major decision, whether in business or in policy reforms, it is often essential to do a thorough evaluation of the pros and cons of a decision to determine possible consequences for the action. This process is obviously not a 'perfect science' because the environment can change which in turn can alter the consequences and outcomes. If a

decision is made to move forward, it then becomes important to determine how best to monitor the outcomes, to minimize the unintended consequences of the action and to consider possible safeguards and alternatives. Not only does one have to consider the consequences for taking an action, but also the consequences for not taking action, something that is often conveniently ignored.

It seems therefore, that the raising and use of 'unintended consequences' has become a routine way for people, organizations, corporations, movements and policymakers to justify action on how not to move forward, for stymieing discussions and preventing any possible resolution on a subject. Today it seems that the use of 'unintended consequences' often has self-serving motivations and goals. This continued trend is troubling in that it prevents transparency and reinforces the 'status quo.'

I have chosen to include this subject because I think that all the stakeholders and parties need to take into consideration the potential important uses of assessing unintended consequences versus its equally potential important abuses.

It brings us back to one of the themes in this paper and that is to stop talking about 'why we can't and shouldn't do something' and start talking about how we do it.

In the end we have to find a way to sort through what are legitimate issues and what are not. It can't be done in a poisoned, adversarial environment where parties refuse to engage in any meaningful discussion.

While many of the arguments of 'unintended consequences' concerning harm reduction seem to be emanating from public health advocates these days the tobacco industry has actually been the master and teacher in the use (and abuse) of such tactics.

A few examples are worth noting:

- When the smoking ban aboard commercial aircraft was being considered, the industry concocted unintended consequences arguments that there would be more smoking in the lavatories increasing the risks of fires, that fights would break out on planes as people were deprived of their needed pleasure to smoke. As the industry has done routinely, they hired 'experts' to make their case.

- When FDA oversight of tobacco was being advocated, the industry used the arguments of unintended consequences to accuse advocates of instigating a 'back door' ban on tobacco – trampling on the rights and freedoms of Americans. They also told tobacco growers that if FDA got jurisdiction, FDA agents would seize their farms and equipment and shut them down. (Side note: The growers eventually became accepting of the FDA jurisdiction over manufactured tobacco products, primarily through a process of dialogue and engagement.)
- When the issue of smoking in restaurants and public places was being discussed, the industry and its allies said that the unintended consequences of such actions would be significant reductions in businesses, cause customers to become irate and again the deprive them of their individual rights.
- When tobacco control advocates proposed restricting advertising and marketing practices that were misleading and deceptive, the industry was quick to conduct campaigns to argue that this would be an infringement on First Amendment rights and a slippery slope to depriving other businesses and Americans of their rights to free speech.

In all of the examples (and there are many, many more) facts were replaced with fiction, rhetoric and hyperbole. Because of the tobacco industry antics and efforts, any meaningful and legitimate discussions and clarification of the issues became impossible.

I have noted elsewhere in this paper that we as a society are confronted with many risks and need to make choices about how we deal with those risks. While 'purist approaches' to the ills confronting society are often meritorious to many, they are often unrealistic at the same time and even threatening to many others in a democratic society.

There are many in tobacco control who, using arguments of unintended consequences are also saying that the only true solution to tobacco's harm is "abstinence only."

We have witnessed a flurry of 'unintended consequences' arguments to make the case that 'nothing' should be done except to continue a 'war,' arguments that include:

- Fears that the mistakes of the low tar and low nicotine fiasco will be repeated – so we need to keep lower risk products off the market.
- Fears that the tobacco industry will continue to use seductive advertising and marketing tactics to encourage children and adolescents to take up the tobacco habit.
- Fears that the development, availability and marketing of reduced risk products will serve as a gateway to the use of higher toxic cigarettes, and prevent those who might otherwise quit from quitting.
- Fears that any positive action, change or position on the part of anyone associated with the industry will be seen as having been designed to establish 'legitimacy' for tobacco.
- Fears that incremental change (even if successful) will take the focus away from the need for comprehensive reforms and further legitimize the industry.

In many ways these are the same kinds of arguments that could be used in a variety of other areas that we confront in our daily lives. With the obesity epidemic quickly approaching the morbidity and mortality rates of tobacco, do we now say that foods should not be labeled for cholesterol, fat, and sodium because of the unintended consequences of people eating more of those foods and exercising less? Does developing safer cars mean that people will drive more recklessly and not use their seat belts possibly increasing the number of deaths and injuries in the total population? Does sexual education and the advocating of the use of condoms, birth control and other measures encourage adolescents to engage in more sexual activity and should therefore be prohibited?

Although I find merit and a critical need to ask important questions about the prospects of 'unintended consequences', I remain concerned when I see such arguments now being routinely raised to promote self-serving agendas and to prevent any real discussion of the issues from taking place. Again, I suggest that we focus on how to move forward taking into consideration legitimate unintended consequences rather than using such arguments as a justification for no action and no real discussion.

Summary and Conclusion

In the last section of this paper I will suggest some ways to deal with the issues of corporate funding and corporate accountability both in terms of harm reduction efforts as well as other broader issues related to tobacco. The issue is not whether I like the tobacco industry or not or whether I like the pharmaceutical industry. The issue is what are the standards of transparency, accountability and integrity which are expected from all of the stakeholders and players? Are there rules and standards? Should there be rules, standards and guidelines? Who should help define those rules, standards and guidelines? What allows one entity to take tobacco money (under certain restrictions) and disperse to others in the field who under other circumstances would chastise and criticize others for taking such money? What allows those who vehemently oppose the taking of corporate money from the tobacco industry to readily take money from the pharmaceutical industry? What is the responsibility of the public health community to encourage and foster discussion and dialogue even if it does not meet their self-serving interests? How do outside influences and money impact on the decision making within the public health community? These are all questions that must be confronted as we deal with the future of harm reduction.