abstract: Undertreated pain and the prevention of prescription drug abuse are significant public health challenges facing the pain and regulatory communities. Although opioids are often effective in treating chronic pain, these same products have also been associated with an alarming increase in morbidity, mortality, and pharmaceutical diversion. State and federal law enforcement efforts to reduce the harms associated with diversion have achieved some success, but some of these well-intentioned investigative efforts have also negatively impacted the treatment of pain by having a chilling effect on prescribers. Subsequent joint efforts between the medical and regulatory communities to reduce the fear of investigation have been short-lived. Consequently, the question becomes whether such policy efforts are viable in the long run, especially when we consider the unique nature of law enforcement and its investigative function. In an effort to answer this question, the following examines the 2004 Frequently Asked Questions consensus document in general and the Balanced Pain Policy Initiative’s 2009 Policy Brief and Procedural Template in particular, discussing their history, impact, and the viability of future reforms. The article concludes that, while balanced policies remain possible between the enforcement and medical communities, they will require open dialogue and on-going collaboration.
REGULATION AND THE NECESSITY OF BALANCED POLICIES

Federal and state governments have a long history of intervention in the regulation of drugs and the practice of medicine. The labeling of pharmaceutical products and the licensing of health professionals had a positive impact on public health by reducing the wide availability of morphine, heroin, and the proliferation of unlicensed healthcare providers (snake-oil salesman) in the early 1900s. Regulatory and law enforcement efforts have the potential, much like any treatment, to result in unintended outcomes by negatively impacting prescribing and the treatment of pain. A classic example of such a phenomenon was demonstrated by the Sigler et al study in 1984 when researchers found significant reductions in Schedule II and III prescribing immediately following the implementation of a triplicate prescription monitoring program. In an effort to counteract these unintended side effects of governmental intervention (medico-legal iatrogenesis), leaders in the pain community advocated for the creation of balanced policies—policies which ensure appropriate access to prescription drugs while at the same time prevent abuse. The 2004 Frequently Asked Questions and the 2009 Policy Brief and Procedural Template (PBPT) represent such attempts and are examined here, with particular emphasis on the more recent 2009 PBPT.

AN EFFORT AT BALANCE: The 2004 FAQ

In recognition of the chilling effect that law enforcement investigations and prosecutions can have on legitimate pain treatment, a joint effort between 21 healthcare organizations and the federal Drug Enforcement Administration (DEA) resulted in the publication of a consensus document: Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel (hereinafter, FAQ). The document, published in August of 2004, “addressed risk assessment, how opioid treatment works, patient behavior, abuse, addiction, rules and laws, and clear descriptions of how and why the DEA may prosecute a clinician.” The title page indicated that the consensus document was “Supported by Drug Enforcement Administration, Last Acts Partnership, Pain & Policy Studies Group [of the] University of Wisconsin” and, when the guidelines were made public, was “embraced” by the head of the DEA. Unfortunately, less than 2 months following its release, the DEA withdrew support for the FAQ, claiming it “contained misstatements.” Although the DEA could have arguably worked with the 21 healthcare organizations to correct any misstatements, they declined to elaborate on what those misstatements were. (Coincidentally, immediately prior to the DEA’s withdrawal from the FAQ, a physician had used the FAQ in his defense of federal charges stemming from his prescribing practices). Eventually, the DEA articulated its concerns with the FAQ by publishing a statement in the Federal Register that, among other things, reasserted their authority to conduct investigations of prescribers on the basis of mere suspicion:

...it is a longstanding legal principle that the Government “can investigate merely on suspicion that the law is being violated, or even just because it wants assurances that it is not.” United States v. Morton Salt Co., 338 U.S. 632, 642–643 (1950). It would be incorrect to suggest that DEA must meet some arbitrary standard or threshold evidentiary requirement to commence an investigation of a possible violation of the Controlled Substances Act (CSA).

The University of Wisconsin’s Pain & Policy Studies Group objected to the DEA’s actions but removed the consensus document at the DEA’s request.
“...SEVERAL [ROUNDTABLE] MEMBERS COMPLAINED THAT, WHILE THE POLICY BRIEF AND TEMPLATE WERE GOOD IDEAS, THERE WAS NO MECHANISM FOR UPDATING, AND MORE INFORMATION SHOULD HAVE BEEN INCLUDED... SOURCES OF DIVERSION, ALTERNATIVES TO OPIOIDS, THE PROPER ROLE OF PRESCRIPTION MONITORING PROGRAMS IN MEDICAL PRACTICE AND DATA MINING BY LAW ENFORCEMENT OR REGULATORY PERSONNEL.”

ANOTHER EFFORT AT BALANCE:
The balanced pain policy initiative’s 2009 policy brief and procedural template

In 2006, two years after the DEA’s withdrawal from the FAQ, the Balanced Pain Policy Initiative (BPPI) was formed in an effort to restart the national dialogue between the enforcement and medical communities. In 2008, the BPPI published a study which examined the frequency of physician prosecutions, and in 2009, the same group released the PBPT. The policy brief and procedural template were contained within one document and were intended to raise awareness about the potential impact that investigations have on legitimate prescribers and their patients and serve as a guide for law enforcement. The publication, Balance, Uniformity, and Fairness: Effective Strategies for Law Enforcement for Investigating and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice, was informed by a 27-member Law Enforcement Roundtable that met in 2008, made up of national figures from the medical, regulatory, and legal communities. The title page of the publication listed 3 organizations associated with the publication: the Center for Practical Bioethics (CPB), the Federation of State Medical Boards (FSMB), and the National Association of Attorneys General (NAAG). The document contained information about the history of the BPPI, the Law Enforcement Roundtable’s membership, a list of effective strategies for law enforcement (eg, the need to distinguish between criminal behavior and medical negligence, balancing publicity, having access to experts, using technological aids, collaborating with agencies, and using educational resources), and a procedural template to assist law enforcement in assessing whether the conduct was criminal, civil, administrative, or perhaps not even actionable. Copies of the PBPT can be located on the websites of the FSMB or the Center for Lawful Access and Abuse Deterrence (CLAAD). (Note: A Google search also revealed links to the publication at NAAG and CPB; however, neither of the links was found to be working at the time of the search.)

DID THE PBPT SUFFER THE SAME FATE AS THE FAQ?
An examination of its history and impact

Following receipt of research funding, a study of the 2009 PBPT was initiated to examine its impact and explore the viability of such joint efforts in the future. This case study received approval from Purdue University’s institutional review board for research involving human subjects (#1209012696). The study was in 2 phases: the first phase would involve interviews with the members of the Law Enforcement Roundtable; the second phase would use a survey of attendees at a regional training conference hosted by the National Association of Drug Diversion Investigators (NADDI) in an effort to measure the impact of the PBPT 4 years after its publication.

PHASE 1: Roundtable interviews

The intention was to interview all members of the Law Enforcement Roundtable (particularly the 27 from the 2008 meeting, the group that informed the creation of the PBPT and whose members are listed on page 15 of that document). A review of those members from the 2008 meeting indicated the following profile: federal DEA (2 members); CPB (2); nonprofit, private organizations (medicine or...
Potential respondents were first contacted by email, a communication medium that enabled the introduction of the research focus, the source of funding, the voluntariness of their participation, the ability to remain anonymous, and the intended interview questions. While some of the questions evolved over time (consistent with qualitative research designs), the main focus was on the following:

- How did they become involved in the project?
- Were there significant disagreements?
- How did the template come about?
- Was the PBPT circulated prior to publication, and how was it distributed after publication?
- Did any law enforcement agencies adopt it?
- What did they think of the PBPT today, and is there anything they would change?
- Are balanced policies with law enforcement viable in the long run?
- How should law enforcement access experts in pain management?
- Was there a process for updating the PBPT?
- How were the members of the Roundtable chosen?
- In light of the absence of actual investigators on the panel, was the actual purpose of the project an effort to restart the dialogue at the national level?

During this initial stage involving contacts and interviews, it soon became apparent that most had moved on to other things, and many were no longer associated with the same institutions from 2008. Some of the members did not remember the project enough to comment on it; some agreed to an interview and were quite candid in their assessments; some agreed at first but later changed their minds; some never returned emails or voice messages; and some outright refused. Moreover, some members who were affiliated with the government, past or present, gave the impression that they would like to speak but it was a topic that they could not discuss. While saturation was not reached, continued efforts to ascertain the whereabouts and interview the remaining members of the Roundtable were resulting in diminishing returns. In the end, contact was made with about one-third of the 2008 panel, and, while their responses may not be representative of the panel as a whole, their comments were insightful.

For instance, several indicated that while the BPPI project was worthwhile, it probably could have done more with additional funding (one person described the project as having "one-half of a shoe string budget"). Moreover, several members complained that, while the policy brief and template were good ideas, there was no mechanism for updating, and more information should have been included—such as the sources of diversion, alternatives to opioids, the proper role of prescription monitoring programs in medical practice and data mining by law enforcement or regulatory personnel. Some also criticized the membership of the committee and suggested that more stakeholders should have been brought to the table, although one remarked that at least there was a wide range of ideology among panelists. Remarkably, some on the law enforcement/ regulatory side thought the panel was heavily weighted in favor of the pain community.

When asked about the impact of the PBPT, one member said that they did not think the outcomes were tracked, and none of them could identify any law enforcement agency or association that adopted the PBPT in whole or in part. Moreover, when asked, none of the interviewees knew who law enforcement should contact if they had questions concerning pain treatment (Strategy 3 in the PBPT: Access to Experts), and at least one member added that some regulatory/law enforcement agencies have trouble communicating with each other in the state, let alone the nation (Strategy 5 in the PBPT: Interagency Collaboration). A few emphasized that an updated, user-friendly template should be established, but more along the lines of a voluntary checklist that could serve as a resource, but not one that a legislature should require law enforcement to follow. Although not all agreed that balanced policies created in conjunction with law enforcement are viable in the long run, all seemed to agree that creating such policies can be challenging, especially in the current opioid climate. While the members from the 2008 Roundtable were credited with the production of the PBPT, not all actively participated in the editing process. However, when the document was completed, all members were notified and were asked to assist in its dissemination.

**PHASE 2:**
Pen and paper survey at NADDI conference

In addition to successfully interviewing about one-third of the 2008 Roundtable, an assessment of the PBPT's impact/influence on law enforcement was made by conducting a survey of investigators attending a pharmaceutical diversion investigation conference. In April 2013, an invited talk was presented at the Western Regional NADDI Training Conference in Las Vegas, Nevada, on the need for balance in pharmaceutical diversion investigations. Prior to the talk a written survey was distributed to all 32 attendees along with a copy of the PBPT (all but one attendee completed the survey). Although nonrandom sampling has limited generalizability, and research funds were limited, the survey was administered to the very group that the PBPT was intended to reach: diversion investigators. The survey found that the majority of the attendees, 85% (24/28), had never seen the policy brief and template before; 6 out of 32 had seen it or portions of it before the presentation; and 2 were not sure. Of the 32 that completed
"...MISTAKES BY INVESTIGATORS OR PROSECUTORS WILL BE MADE, AND ANY INVESTIGATION OR PROSECUTION INVOLVING A PRESCRIBER WILL RECEIVE A GREAT DEAL OF MEDIA COVERAGE—ESPECIALLY WHEN CONSIDERING THE CURRENT HYSTERIA ASSOCIATED WITH OPIOIDS, THE PRESSURE ON PUBLIC OFFICIALS TO DO SOMETHING QUICKLY ABOUT A COMPLEX SOCIETAL PROBLEM, AND THE VARIATION AMONG THE STATES CONCERNING INVESTIGATIONS AND THE RELEASING OF INFORMATION."

the survey, their self-identified positions were mixed and consisted of the following: narcotic investigators (15 attendees); retail pharmacy investigators (6); loss prevention personnel and insurance investigators (5 each); analysts and pharmacy auditors (4 each); pharmacy investigators and pharmacists (2 each); and investigator, registered nurse, physician, pharmacy board investigator, fraud investigator, state compliance auditor, and federal prosecutor (1 each). Two of the respondents did not describe their current positions and were recorded as unknown/missing. Of the 6 that had answered YES and were sure that they had seen the PBPT or portions of it before the presentation, only 3 described themselves as investigators. Those same individuals were then asked if they used it during an investigation and none of them indicated that they had.

**DISCUSSION**

When considering the outcomes of the 2004 FAQ and the 2009 PBPT, one wonders whether such future collaborations with law enforcement are possible. Could the relationship between the law enforcement and the medical community be likened to Aesop’s The Scorpion and the Frog, a fable where despite a pre-existing agreement, the scorpion will end up stinging the frog because it is just part of its nature? Yes and no. Any commitment from law enforcement to create balanced policies must be understood in the context of their nature—the need to investigate—even if it means that they too may suffer the same fate as the frog.

First, if the primary task of prosecutors remains the prosecution of offenders, then the primary responsibility of law enforcement is to investigate suspected offenders to determine if an offense has occurred and whether that offense should be presented to the prosecutor’s office. Although investigations are known to have a chilling effect on even legitimate prescribing, it would be difficult for the police to determine whether a crime has been committed and whether it should be prosecuted without investigating the matter first. Unlike prosecutors, who can decide whether to pursue charges following an investigation by law enforcement, the temporal nature of the investigative function does not permit the police to have the same luxury. True, the DEA should have worked with the healthcare organizations to correct any misstatements in the FAQ instead of picking up their marbles and going home, but their subsequent statement in the Federal Register (see quote at beginning of article) illustrates the nature of the law enforcement function and the difficulty in forging lasting agreements.

But having said that, it is also foreseeable that mistakes by investigators or prosecutors will be made, and any investigation or prosecution involving a prescriber will receive a great deal of media coverage—especially when considering the current hysteria associated with opioids, the pressure on public officials to do something quickly about a complex societal problem, and the variation among the states concerning investigations and the releasing of information. Even if the prescriber is ultimately not charged with a crime after being investigated, or is found not guilty or not responsible, the entire
process will often be devastating to the pain community in general and the accused in particular.

That does not mean, however, that the law enforcement community is not answerable for any of their actions, nor does it mean that they would not benefit from an increased awareness of the unintended impact that investigations can have on legitimate prescribing and pain treatment (a goal of the 2004 FAQ and 2009 PBPT). Law enforcement wants to get the bad guys, and the medical community wants to protect the good guys—and their patients in the process. So perhaps the approach should be one of mutual on-going collaboration where law enforcement learns from the medical community about the complexities of pain treatment to reduce the likelihood of targeting a legitimate prescriber, and uses that same information to rebuff the claims of a prescriber who is engaging in criminal conduct.

In light of the relatively short lives of the 2004 FAQ and 2009 PBPT, could the value of both projects have been more about opening the dialogue rather than developing long-standing policies? Although copies of both documents can still be found on the internet, they were ultimately not embraced by the law enforcement community. But as at least one member of the Roundtable pointed out, what may have accounted for their minimal impact was a lack of organizational buy-in. True, the DEA appeared to have signed on for the entire FAQ voyage by virtue of 1) working with the 21 healthcare organizations over the course of a year, 2) permitting their organization’s name to appear as a supporter on the first page of the consensus document and, 3) having the leader of their organization voice support for the document after its release. However, it is entirely possible that the DEA personnel involved in the project from the start may not have possessed the requisite authority to write checks on behalf of the organization. This may also explain why the DEA opted to withdraw from the entire project rather than seek the correction of any mis-statements within the consensus document itself. Moreover, the use of the 2004 FAQ as a defense in a federal criminal prosecution probably reduced the likelihood that the DEA would reconsider their decision to withdraw. The lack of organizational buy-in could also explain the short life of the PBPT and its limited impact on law enforcement. Although prominent figures from across the United States attended the meetings, there was almost a total absence of actual investigators on the Law Enforcement Roundtable. In fact, most of the government personnel who were on the Roundtable were not investigators at all—they were heads of agencies, not individuals who conduct investigations on a day-to-day basis (the intended audience of the PBPT). Consequently, a more charitable assessment could be that the PBPT, like the FAQ, was more about restarting the dialogue than providing a definitive, long-standing guide to law enforcement. Since open dialogue and on-going collaboration is the solution to creating and maintaining balanced policies, future efforts could pick up where the PBPT left off but also involve other stakeholders such as actual prescribers and diversion investigators. This new group could use the 2009 PBPT as a starting point and develop a checklist for law enforcement to consider in their efforts to detect criminal prescribers. Such an approach would balance the needs of law enforcement to conduct investigations of suspected criminals, which is in their nature, while at the same time increase their awareness of the variations in pain treatment and the unintended consequences their actions can have on prescribing. As the landscape changes, on-going collaboration would not only enable continued access to experts, it would also permit updating of the new checklist.

While the foregoing seems reasonable, challenges to making that dialogue and collaboration happen still remain. For example, not all regulatory agencies will engage in dialogue with the medical community (some do not even get along with each other). In fact, it was difficult to even get some government officials to talk about their earlier efforts to restart the dialogue (which is certainly their right, but is alarming in a free society and demonstrates the difficulty of achieving open dialogue and on-going collaboration). But what if, for example, the pain community wants to engage in dialogue but the DEA does not and would rather take their marbles home with them? Surprisingly, regulatory and law enforcement agencies are a lot like children: they all must rely on a parent and do not always get their way. See, for example, the spread of marijuana legalization laws across the United States despite the DEA’s historic opposition. So, if some agency or regulator does not want to have a discussion about balance and implement needed reforms, then people need to call the agency’s parents—elected officials—and have them replaced with someone who does. With over 100 million Americans affected by chronic pain, it is a dialogue worth having.

STUDY LIMITATIONS

This case study was merely one approach to assessing the impact of the FAQ in general and the BPPI in particular. As noted earlier, there was significant nonresponse by members of the Law Enforcement Roundtable due to passage of time, reassignment, reluctance to discuss, and so on. Nonresponse becomes a problem if the views of those who did not respond differed significantly from those that did. Because potential respondents have a right to refuse to participate in any study, determining the views of those who did not participate remains problematic. Secondly, funding for pilot studies are often limited and the relatively small sample size stemming from a purposive sampling method used in the survey of conference attendees limited generalizability of the results. Nevertheless, the data that was acquired provided some valuable insight into the impact of the FAQ and PBPT, as well as the viability of such projects in the future.

CONCLUSION

If the primary goal of the 2009 Balanced Pain Policy Initiative was to restart the national dialogue, they were successful as evidenced by their ability to 1) facilitate meetings between several national organizations and their representatives from the legal, medical, and regulatory communities and, 2) produce 2 publications (a peer reviewed article in Pain Medicine and the PBPT). However, if they also intended for the PBPT to be embraced by law enforcement, the intended audience of the project, it appears that they were less successful. A lack of organizational buy-in could have been a substantial
The issues involved in this article were presented and discussed at 2 professional conferences (PAINWeek 2014 and the Academy of Criminal Justice Sciences in 2013). Funding in support of this study was provided by Purdue Pharma, LP, who had no control or influence in the study’s design, implementation, analysis, or reporting of the results.

References

6. Center for Practical Bioethics. Balance, Uniformity, and Fairness: Effective Strategies for Law Enforcement for Investigating and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice. 2009. [Link no longer available, as noted in this article.]