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 Food and Drug Administration
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 Rockville, MD 20857

June 16, 2005

RESPONSE TO:

Comments by Law Offices of Kleinfeld, Kaplan and Becker, LLP on
 Citizen Petition 2005P-0076

BY

PETITIONER: BARBARA VAN ROOYAN, KIRK VAN ROOYAN, M.D.

Purdue Pharma's attorneys have sent to the FDA twenty three pages to explain, why, in their estimation, Citizen Petition 2005P-0076 should not be approved. The main focus of these comments seems to revolve around *two main perspectives*:

1. That the petitioner does not offer credible evidence for the requests and uses errors of fact and distortions of data to support the requests.

It will be shown that many of Purdue Pharma's comments themselves are based on unsubstantiated or outdated claims and that they convey distortions of fact and perspective through selectivity and omission. Since it is unnecessary to correct each and every misstatement and distortion in order to respond to the substance of the comments, no attempt will be made to do so.

2. That Purdue Pharma bears no responsibility for adverse events that occur if their drug(s) is not used exactly as directed.

Attempts by Purdue to absolve themselves of responsibility for adverse events resulting from both legitimate use and misuse of OxyContin demonstrate a lack of social responsibility and ethics, and a disregard for sound public health policy.

Clarification

Citizen Petition 2005P-0076 contains four requests. Purdue erroneously assumes that requests three and four are being made *in the alternative* to requests one and two, when in fact, all four requests were independent and felt to have equivalent merit. The petitioner is aware that, as stated on the FDA website:

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants.

I. RESPONSE TO PURDUE PHARMA'S REASONS 1-4 WHY THE PETITION SHOULD BE DENIED

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1. Purdue claims that there is no evidence to support the proposition that OxyContin and Palladone are not safe or effective for patients:

In actuality, there is such documentation [1], [2], [3], [4], [5], [6], [7], [8]; in each of these studies, a notable lack of efficacy was demonstrated, and up to 50% of patients experienced side effects requiring additional medications or discontinuance, dependence/addiction problems, and/or withdrawal symptoms. Indeed, it is these very problems that are largely responsible for the relative paucity, but not absence, of long term data alluded to by Respondent. These limited results do, however, support the actual point made by Petitioner and glossed over by Respondent: considering that OxyContin has been shown to be no more effective than other opioid analgesics; that more recent (2003-2005) reports have demonstrated a higher addiction rate for OxyContin; that because of its easily overridden sustained-release formulation, one tablet of Oxycontin is potentially fatal; and that PurduePharma has made insufficient responses to sanctions by the FDA for improper marketing, additional restrictions and control measures, including those proposed by Petitioner, are warranted.

2. Purdue alleges that a majority of criticism against OxyContin is based on individuals using the drug without medical oversight for non-medical purposes:

There is, however, considerable evidence of adverse effects among patients legitimately prescribed OxyContin; examples can be found on www.oxyconned.org, www.oxyabuse.kills, www.oxydeaths.com. Recently, U.S. Representative Stephen F. Lynch (D. Mass.) stated that 56% of all OxyContin addictions occur in such patients, a figure magnified by the facts that: (1) over half of these prescriptions were written by primary care physicians [9] --the known priority marketing focus of Purdue--most of whom are inadequately trained in modern pain therapy, (2) many of these patients, to treat side effects of OxyContin or co-morbid problems, are also on other, often psychotropic, drugs, to which Purdue has erroneously attributed reported addictions or deaths [10], [11], and (3) due to Purdue's concerted and inappropriate marketing efforts, the total number of OxyContin prescriptions written is huge.

3. Purdue raises the issue of "inconsistencies in sound public health policy":

Sound public health policy includes a responsibility to address all sources, causes, and contributing factors to drug addiction and adverse effects from drugs legitimately prescribed; law enforcers, educators, physicians, pharmacists, parents, policy makers, **AND drug companies** all have this social and ethical obligation. Purdue references OxyContin as "safely used", apparently dismissing evidence that nearly half of patients prescribed the drug fail to take it as directed, that a study of 11,000 pain clinic patients found that 40% of the legitimately prescribed OxyContin was recycled among other clinic patients and 15% had no evidence they had even taken the drug [2], and that the company was admonished by the FDA that "your [medical] journal advertisement are misleading because they...omit...crucial facts...[12]. For PurduePharma to camouflage

its own "isolationist" approach to the realities/ramifications of OxyContin by so labeling Petitioner's requests is not only untenable but hypocritical.

4. Purdue alleges that Petitioners' requests would have no effect on the overall problem of substance abuse in this country, and limit alternative therapies:

The Petition does not claim to address the overall problem of substance abuse in this country. It does claim to address, in part, the overall problem of addiction and death by OxyContin and the potential for such with Palladone. It requests changes which, both logically and empirically, would reduce both the incentives toward and danger from abuse (**chemical reformulation**), and would decrease legitimate access in a population shown to be more prone to abuse [10]—chronic non-cancer pain patients (**narrowing of indications**). Further, other than the issue of dosage convenience—and even this is less than clear-cut—there is no objective evidence that Petitioner's proposals would compromise medical professionals' ability to treat pain. By adjusting toward a more scientific approach to pain management, the proposals would, on the contrary, expand the use of alternative treatment modalities —e.g. counseling, physical therapy, etc.

II. RESPONSE TO PURDUE'S COMMENTS ON REQUESTS ONE AND TWO OF THE PETITION (Temporary recall of OxyContin and Palladone until reformulated to drugs of minimal abuse potential)

A. Purdue states that petitioners have not provided evidence that OxyContin and Palladone are neither safe nor effective.

As already cited in I-1. above, statements by PurduePharma attesting to any unique effectiveness of long-term OxyContin and Palladone for chronic non-cancer pain have not been substantiated by current published data, and there is even stronger recent evidence of the drugs' lack of safety. Further, it is documented that Purdue has contributed to this problem through its systematic and aggressive marketing of OxyContin to physicians who have inadequate skills in all aspects of pain management, its relentless, misguided efforts to expand the use indications for the drug, and its repeated misrepresentations of risks and addiction potential [10]. That this situation is real and has reached crisis proportions is manifested by several recent events: legislation introduced in Massachusetts and the U.S. Congress (H.R. 2195) to withdraw OxyContin from the market; grand jury proceedings in Virginia to indict executives of PurduePharma for fraudulent representation; a federal judgment (Manhattan) for misrepresentation of OxyContin's pain efficacy; a lawsuit by the city of New York for alleged price inflation of the drug to Medicaid patients. These occurrences expose the lengthy delineation of its legal successes contained in Purdue's response to Petitioner for what it is: a testimony to the talents of the company's attorneys

and its financial assets, and a measure of its desire to avoid accountability, not a reflection of the truth about the effectiveness and safety of OxyContin.

Purdue also claimed in their response to Petitioner that a GAO Report (GAO-04-110) stated "we could not assess the relationship between the growth in OxyContin prescriptions or increased availability and the drug's abuse and diversion..." What Purdue conveniently omitted was this additional statement from the report: "However, limitations on the abuse and diversion data *prevented* an assessment of the relationship between the availability of OxyContin and areas where the drug was abused or diverted"[13]. Thus, the report did not state a **lack of relationship**, only that **no assessment could be made**. Additionally, "The rapid growth in OxyContin sales, which increased the drug's availability in the marketplace, may have made it easier for abusers to obtain the drug for illicit purposes"[14]. It is hard to assess this part of Purdue Pharma's response as anything other than self-serving contextual editorializing.

Purdue Pharma claims that the October, 2003 Orlando Sentinel series of articles was fraught with errors and distortions and that the paper ran subsequent corrections. In September, 2004 the San Diego Union Tribune ran a series of articles on prescription painkillers, including OxyContin. Part I of this series was titled "Accidental Addicts", referring to "a growing number of people who accidentally became hooked on drugs prescribed by their doctors for medical reasons"[15]. There were no corrections run for any part of the series, and there have been a substantial number of similar articles in newspapers across the nation and in the broadcast media which have negatively but accurately represented the marketing practices, safety and addiction risks, and questionable long-term efficacy related to OxyContin. In this section Respondent has thus portrayed the exception as the rule in its effort to undermine the worth of Petitioner's requests.

With regard to PurduePharma's discounting the increasing incidence of patient deaths from OxyContin because of the presence/role of other drugs, an ongoing study of medical examiner data regarding OxyContin describes standard OxyContin treatment regimens, then goes on to say that: "*by these treatment designs a "normal" patient receiving standard OxyContin prescription regimen approved by the FDA may be a poly-drug user. One treatment strategy recommended for 'chronic pain' patients is the co-administration of opioids with anti-depressants - again, a treatment strategy, by its design, that results in polydrug usage. With these facts in mind it was not surprising to find many of the OxyContin deaths were associated with polydrug toxicology. This does not minimize the significance of the role of OxyContin in these deaths.*"[16] Once again, Purdue has engaged in "creative" logic to support its response. The presence of multiple drugs found in autopsy reports does **not** refute involvement of OxyContin in causing these deaths; it only reaffirms the medical inappropriateness and danger of combining the drug with other psychoactive drugs in a group of chronic pain patients who have a proven higher incidence of mental health issues, addiction/dependency, abuse, and overdose.[10], [17]

As an admittedly more personal response to the alleged "deficiencies" in Petitioner's comments about OxyContin's safety and efficacy, Thom Heugel of Sparta, Michigan [18] has authorized inclusion of the following (paraphrased):

While going to school to get my degree I worked several different jobs to pay the rent and schooling. One of these jobs was as a policeman in the metro Atlanta, GA area and in the line of duty I sustained two injuries, both to my left knee. Years later I worked for a wholesale cookie company and sustained another injury to my left knee while climbing up the back of the truck. I also worked for 28 years as a paramedic and my knee took a beating. Eventually I ended up having five arthroscopic surgeries and two total reconstructions. Because of continued pain I went to a pain clinic in Grand Rapids Michigan that was highly rated. They started me on Vicodin and physical therapy. After several different medications, including methadone they put me on OxyContin. I have been on OxyContin now for about 4 ½ years. The maximum dosage that my doctor had me on was 160 mg., and there I plateaued. I began to need the OxyContin more frequently. It started out that I could take the dosage up to 2-3 hours late with no real problems but now if I take it even 45 minutes late I begin to have withdrawal symptoms and they aren't pretty to see. My body screams for the OxyContin. I do not want to stay on this drug; it is making my life hell. Constant fatigue, constipation to diarrhea, short term memory losses and then other medications to counteract the side effects of the OxyContin. But getting off of it is hell in itself. My doctor and I have slowly been reducing my dosage so that I am now down to 20-30 mg. a day but even at this low dose I experience severe withdrawal and I just cannot seem to go any lower than this. Never would I have gone on the OxyContin in the first place if I knew it was this addicting. I have read a lot of literature on Oxycontin, and in many of the deaths they state multiple medications in the victims blood system. Well, of course there are. The doctors often prescribe other meds along with OxyContin and drugs to address the side effects of the drug Oxycontin. I want my life back. I only hope that I do not become another statistic.

Whether this is a story of addiction or physical dependence is a moot point. What cannot be debated is that it is a tragic, but very real, testimony to the adverse effects of legitimately prescribed OxyContin which has resulted in a life virtually destroyed.

B. Purdue claims that the alternatives proposed by the Petitioner would not provide the same clinical benefits as OxyContin and Palladone.

Purdue refers on page nine of their comments to an international treaty declaring the duty of the United States to make effective opioid analgesics available to its citizens. This treaty

was written in 1961 and amended in 1972 at a time when these drugs were used exclusively for cancer patients and not for the general patient population. This constitutes yet another example of selective editing by Purdue in its response to Petitioner.

Purdue also claims that Petitioner has incorrectly interpreted clinical studies of controlled-release hydromorphone and controlled-release oxycodone [3],[4],[5],[6],[7],[8], stating that the studies weren't meant to evaluate therapeutic advantages of controlled-release dosage because the study employed *optimal fixed-schedule dosing* (drugs taken exactly as directed) of the immediate-release formulations. However, the study does show CR opioids are no more effective than IR opioids when the latter are taken as directed. Respondent's assertions that "break-through" pain and some loss of functionality is more prevalent with IR opioids are correct, but their claims about the degree of impact of this are overstated, especially considering that other CR preparations such as MS Contin would still be available. When viewed in the larger, and proper, perspective of the gains realized from chemical reformulation of OxyContin and the short time period required to achieve this (see below), the "loss of clinical benefit" to pain patients predicted by Respondent would more accurately be described as a "loss of financial benefit" to Purdue Pharma.

C. Purdue claims that pain patients would be deprived of medicines during an extensive time period.

If manufacture of an abuse-deterrent formulation were truly a priority for PurduePharma, there would in actuality be no need for an "extensive" down time. David Haddox and Curtis Wright (both employees of Purdue Pharma) currently hold a patent (#6,696,088) for tamper-resistant oral opioid agonist formulations, and the company certainly has the means and resources to bring an abuse-resistant formulation to the market quickly.

Purdue claims that developing an abuse-resistant pain medication requires enormous investment, not only of money but also of time, and states that \$150 million has thus far been expended in this development. Considering that this amount is approximately 1% of one year's revenue from OxyContin alone, it hardly constitutes "an enormous investment". Purdue also states that work on the development has been ongoing and "top priority" since 1996. It is difficult to believe that in nine years Purdue Pharma has not been able to do what Pain Therapeutics Inc. has done in six years (and at considerable less cost than \$150 million). According to Christine Waarich, Senior Manager of Investor Relations, at Pain Therapeutics Inc., Remoxy (an abuse-resistant form of OxyContin) is now in its second Phase III clinical trials. These will be concluding at the end of 2005, at which time data will be submitted to the FDA. PTI has taken three drugs to Phase III clinical trials in six years for less than \$100 million.

Contrary to Respondent's arguments in both B. and C., then, there is no credible evidence that favorable action on this aspect of Petitioner's request would mean "sacrifice of good patient care..." either with regard to lack of comparable drug availability or excessive time delays.

D. Purdue claims that if OxyContin and Palladone are removed from the market, there would be no reason not to take other oral opioids off the market as well.

OxyContin is two times the strength of morphine, and Palladone is approximately seven times stronger than OxyContin, indicating a greater chance of adverse effects in both legitimately prescribed pain patients and those who misuse or abuse the drugs. As previously documented, recent studies have shown OxyContin to have more addictive potential than most other types of opioids. Unlike all other opioid preparations, OxyContin and Palladone medication guides contain the words "fatal" and "death" (10 to 12 times), and the Palladone guide refers to "fatal overdose with first dosage".

The results of the 2004 "Monitoring the Future" study funded by the National Institute on Drug Abuse (NIDA) and conducted by the University of Michigan, indicate that illicit OxyContin use among eighth, tenth and twelfth graders has increased from 2002 to 2004 [19]. The abuse of Vicodin, while overall used more than OxyContin for these three groups, has actually decreased over the same time period. This study involved 49,474 students from 406 public and private schools across the nation.

Respondent's erroneous implication seems to be that because its products are in the same DEA class, they are also pharmacologically indistinguishable from other types of oral opioids; it is interesting to note that the actual and substantial biomedical differences of their products are promoted by PurduePharma when it comes to sales and marketing

III. RESPONSE TO PURDUE'S COMMENTS CONCERNING REQUESTS THREE AND FOUR OF THE PETITION (Limiting indications for OxyContin and Palladone to "severe chronic pain from peripheral disease processes")

A. Purdue states that the "moderate pain" part of the indications for OxyContin and Palladone is appropriate.

While PurduePharma correctly does not include "commonplace and ordinary aches and pains" as moderate pain, its inclusion of "pain that interferes with the patient's ability to function normally" as moderate is more troubling, particularly when juxtaposed against the company's additional "when a continuous, around-the-clock analgesic is needed for an extended period of time" portion of its indications. While these descriptions are appropriately subject to interpretation by medical professionals, common sense and extensive clinical experience would not link most moderate degree pain situations with long term, continuous opioid analgesic need/usage.

More germane to Petitioner's argument—once again downplayed by Respondent—is the deleterious effect that Purdue's unfounded and inappropriate marketing practices have had on stretching/blurring the indication boundaries of prescribing physicians. By

misrepresenting OxyContin/Palladone as virtually without risk/addiction potential and minimizing the incidence of bothersome side effects, the company, intentionally or not, has expanded the purvey of its drugs beyond even its own indication parameters. Despite Respondent's statements to the contrary, this is the undeniable reality. Evidence has already been cited [10], [17] regarding the higher incidence of associated psychological factors in these chronic non-cancer pain patients. According to addiction medicine specialist Stephen G. Gelfand, M.D. [20]:

"In the 'rush to opioids' for all types of chronic pain, the role of psychiatric co-morbidities, which predispose to opioid abuse, addiction, and overdose, have frequently been ignored. All too often, opioids have become a poor and dangerous substitute for appropriate mental health care, and are often used to treat patients labeled with inaccurate or erroneous physical diseases. However, progressive management in both behavioral and addiction medicine has shown that many patients with chronic non-cancer pain benefit from learning strategies to self-regulate anxiety and mood while eliminating or controlling non-productive cognitive processes. This can help break the mindset of using risky external substances such as opioids to attenuate intolerable subjective states, including pain"

Respondent also refers to the undertreatment of pain as a "severe" public health problem in the U.S., and claims that according to the NIH, patients can be treated with opioid therapy without developing tolerance, addiction or toxicity. Petitioner does not argue that pain is probably still undertreated in the U.S., but a recent study [21] has shown that the factor previously felt to be the primary barrier to adequate pain treatment—physicians' fear of disciplinary action by medical boards—is, in fact, not. In the entire U.S., only an average of 120 physicians annually were sanctioned for opioid prescribing, and every one had associated violations (incompetence, sexual activity, etc.). It is reasonable to expect that this information will favorably impact undertreatment of pain in the near future, which calls into question Respondent's assessment of this issue, one that, in any case, cannot be a rationale for injudicious pain management (as Respondent intimates).

As pointed out by Russell Portenoy, M.D., a consultant for PurduePharma and a pain expert, there is now a need, based on data from the last two years, to move from previous minimizing and dismissal of risks of abuse, addiction and diversion of opioids to a focus on these very real issues [22]. Dr. Portenoy emphasizes that "doctors have to have two sets of skills to use these drugs safely and effectively, or they shouldn't use them...how to assess the risk of abuse and diversion and addiction, and how to structure the therapy so that they minimize that risk." It is also time to look more closely at how the undertreatment problem is being addressed, and, as pointed out by Dr. Gelfand, to realize that there are many underutilized non-drug modalities that are effective for pain, and that many chronic non-malignant pain patients would benefit as much, if not more, from these modalities, and with far fewer adverse effects.

Overall, then, Respondent: describes what "moderate" pain isn't but doesn't define in even quasi-medical terms what it is; defends PurduePharma's drug indications as

appropriate because “moderate” pain patients sometimes have severe pain and tend to underreport their pain degree (without providing any support data for the validity of these “reasons”), and because pain in general has historically been undertreated; asserts that limiting drugs described by Purdue itself as for “when a continuous, around-the-clock analgesic is needed for an extended period of time” to severe pain only is inappropriately restrictive; discounts the established additional risk of adverse events created by promoting OxyContin and Palladone for the chronic non-cancer pain patients who comprise the majority of the “moderate” pain population; and contends that it should be acceptable to medical professionals and the public for both drugs to be used “without regard to a specific disease state or origin of pain”(see below). It is primarily because Respondent and PurduePharma do not acknowledge that all these perspectives regarding the indications for use of OxyContin and Palladone are inappropriate, logically and scientifically flawed, and irresponsible that Petitioner believes that requesting enforced narrowing of the drugs’ indications through the FDA is not only justified but mandatory.

B. Purdue states that limiting the use of OxyContin and Palladone to pain from documented peripheral tissue disease is untenable and would be inhumane.

This statement is based upon false assumptions by Respondent; the terminology used by Petitioner—“documented peripheral tissue disease”—was not intended in the strict context taken by Respondent (and probably needs further refinement). Rather, it was derived from the same IASP definition of pain referenced by Respondent (pg.16), which confirms the value of separating acknowledged pathological tissue disease/damage states with anatomic abnormalities--e.g. cancer, brain/spinal cord/nerve damage, end-stage arthritis, etc. [all most commonly peripheral, although central lesions also occur]--from those of dysfunctional stress-related syndromes often with psychosocial variables-- e.g. fibromyalgia, tension headache, non-structural low back pain, anxiety syndromes, depression, etc. [mostly central and related to neurophysiological changes in the brain, without currently accepted pathological tissue disease findings]. [23].

Respondent’s comments regarding the term “documented” also lack validity because they focus on only part of the subjective reality of pain as a medical entity. It is true that “there is no [objective] test --whether medical or psychological- that can unequivocally document the presence or absence of pain or, if it is present, its severity”, but it is precisely because of the interpretive difficulty of that subjectivity and its ramifications for responsible and effective treatment, essentially ignored by PurduePharma, that the separation - documentation proposed by Petitioner has merit. In the face of the now substantial confirmations referenced elsewhere in this document that “...pain in the absence of tissue damage or any likely pathophysiological cause usually...happens for psychological reasons.”[23] and that there is an increased risk of addiction, abuse, and overdose in such patients[10],[17], for Respondent to misconstrue and dismiss “documentation”--accurate diagnosis has, after all, been a core component of the practice of medicine for centuries--as “having no rationale” because it is less clear-cut in this area and justifies PurduePharma categorizing pain as a “disease unto itself” is not only

another instance of the selective focus that permeates their overall response, but also unconscionable.

In light of the above, it is ironic that Respondent labels Petitioner's standard of "documented" as "potentially detrimental to patient care" and "inhumane". It would seem those designations more properly apply to an approach to pain management that misleadingly promotes the across-the-board use, without research-based patient selectivity criteria or evidence of long-term efficacy/safety, of powerful analgesics—OxyContin and Palladone—which have been demonstrated to have several higher than average risk factors, including one that can be fatal and which the company erroneously alleges is "years" away from correction.

C. Purdue states that its Risk Management Programs are "comprehensive".

Petitioner does not criticize PurduePharma's RMP structure, oversight, or implementation. We do, however, take issue with some of the Respondent's accompanying comments in this section, particularly that OxyContin is not a cause of drug abuse, but is, in essence, a passive participant in the larger escalating illicit drug problem nationwide. Such an assertion in view of the demonstrated misleading marketing information provided by PurduePharma, its aggressive promotion of OxyContin for "shotgun" treatment of most moderate pain--short-term or long, and its inadequate response to the problem of sustained-release "override", is out of touch with reality and self-effacing.

IV. SUMMARY AND CONCLUSION

In his negative assessment of the Petition, Respondent has stated that Petitioner "has failed to identify the true nature of the problem", that their requests are "misguided" and "would jeopardize the medical care of pain sufferers", and that "OxyContin is not the problem upon which national health policy in the area...of prescription drug abuse and diversion should focus.". Respondent's support for these points of view has been shown in this response to be insufficient and unsatisfactory; it has not embodied arguments based on unbiased, realistic, and thorough assessment of pertinent scientific data, medical and pharmacologic facts/principles, or human and social priorities. Rather, it has consisted largely of self-serving representations of: parts of issues as the whole, irrelevant aspects of the problem as important/germane, unsustainable and illogical conclusions and perspectives as reasonable/proper, and distortions and denials regarding PurduePharma's behavior and responsibilities in the OxyContin situation as veracity.

As we indicated at the beginning of this response would occur, Petitioner has provided adequate documentation and refutations to reinforce the merits of its four Petition

requests. Irrespective of the "smoke and mirrors" methodology utilized by Respondent, **the truth of the OxyContin matter and PurduePharma's role in it is:**

1. OxyContin and Palladone possess pharmacologic properties that have been shown to produce increased risk of adverse events—dependence/addiction, unfavorable side effects, and abuse—in the chronic, non-cancer, "moderate" pain patient population. In addition, PurduePharma's claims regarding the efficacy of the drugs relative to other opioid analgesics have not been substantiated.
2. PurduePharma's marketing of these drugs has been overly aggressive and irresponsible—misleading physicians about risks and efficacy, focusing on doctors who are inadequately skilled in pain management—and has inappropriately expanded the use of OxyContin in the "moderate" pain group, thereby aggravating the risk potential of the drug.
3. Despite efforts by the FDA to induce voluntary changes in its marketing behavior, PurduePharma's response has been inadequate both in terms of actual focus and acknowledgment of ethical /social accountability.
4. The current easily bypassed sustained-release chemical formulation of OxyContin has contributed significantly to its abuse and danger; PurduePharma has not sufficiently prioritized its response to this problem, has misrepresented the time frame required to correct it, and has subordinated its ethical/societal responsibilities in this area to its financial welfare by not temporarily withdrawing OxyContin from the market.
5. PurduePharma has largely ignored both the guidelines of the International Association for the Study of Pain and the medical profession's "gold standards" of accurate diagnosis and patient selectivity criteria, instead promoting pain as a "disease unto itself" in order to market OxyContin and Palladone.
6. When challenged on its scientific, marketing, and ethical perspectives, Purdue Pharma has engaged in innuendo, half-truths, stonewalling, and legal gymnastics instead of responding in a professional and conscientious manner.

Taken as a whole, these truths emphatically demonstrate that "when you're not part of the solution, you're part of the problem". Further, they verify that Petitioner's requests to the FDA are not only well-founded but that, given Purdue Pharma's conduct, they are the only effective option if the human, economic, and societal damage inflicted by OxyContin, currently in considerable excess of its benefits, is to be halted.

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