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IN THE SUPERIOR COURT OF THE STATE OF ARIZONA
IN AND FOR THE COUNTY OF PIMA

STATE OF ARIZONA, *ex rel.* TERRY GODDARD, Attorney General,

Plaintiff,

-vs-

PFIZER INC,

Defendant.

C20087337

Case No: _____

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

(Unclassified Civil)

PAUL TANG

1. Attorney General Terry Goddard, on behalf of the State of Arizona, brings this civil action in the public interest against DEFENDANT PFIZER INC for violating A.R.S. § 44-1521 et seq., as follows:

PARTIES

2. Plaintiff, the State of Arizona, represented by Attorney General Terry Goddard, who brings this action pursuant to the authority granted under A.R.S. § 44-1521 et seq.

3. Defendant Pfizer Inc, ("Pfizer") is a Delaware corporation with its principal place of business in New York. At all relevant times, Pfizer did business in the State of Arizona

selling and promoting prescription drugs, including Bextra® and Celebrex®. In 2002, Pfizer purchased Pharmacia, a Delaware corporation, and merged the two companies' Bextra® and Celebrex® sales forces. Prior to this sale, the two companies' co-marketed Bextra® and Celebrex® and closely coordinated all promotional efforts. In addition for its own conduct marketing Bextra® and Celebrex®, Defendant Pfizer is also responsible for Pharmacia's conduct. The conduct of both Pfizer and Pharmacia shall hereinafter be referred to collectively as conduct by DEFENDANT.

4. DEFENDANT at all relevant times has transacted business in the State of Arizona. The violations of law alleged herein have been and are being carried out within the State of Arizona.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter and DEFENDANT of this action pursuant to A.R.S. § 44-1521 et seq. Venue is in Pima County, Arizona.

SUMMARY OF THE ACTION

6. The State filed this Complaint because DEFENDANT engaged in repeated deceptive acts, methods and practices with the purpose of achieving greater sales of Bextra® than it otherwise would have been able to achieve had they complied with the law. DEFENDANT achieved these sales in large part by misleading physicians and health professionals, consumers and others about the safety and efficacy of Bextra®, and about the indications for which Bextra® was approved.

7. DEFENDANT'S unlawful marketing of Bextra® began in 2001 after the U.S. Food and Drug Administration ("FDA") declined to approve Bextra® for all of the uses and indications that DEFENDANT were counting on to make Bextra® a financial "blockbuster." Rather than simply marketing Bextra® for the more limited FDA-approved indications, DEFENDANT engaged in an aggressive, deceptive, and unlawful "off label" marketing campaign to increase sales of Bextra®, a COX-2 inhibitor, to treat acute pain, perioperative pain

and opioid sparing uses. These indications or uses for Bextra® are referred to as "off-label" uses because they have not been approved by the FDA. Bextra®'s FDA-approved "on-label" use is limited to 10 milligram doses for the treatment of pain associated with rheumatoid arthritis and osteo-arthritis and 20 milligram doses for pain associated with primary dysmenorrhea (menstrual pain).

8. As a part of it's "off-label" campaign, DEFENDANT misrepresented that Bextra® was a safe alternative to schedule 2 narcotics and traditional nonsteroidal anti-inflammatories ("NSAIDs") typically used in the treatment of acute and perioperative pain, marketed Bextra® as reducing serious gastrointestinal side effects without possessing competent and reliable evidence to support this claim, and failed to disclose that Bextra® increased the risk of serious adverse events including death.

9. DEFENDANT also commissioned and disseminated hundreds of thousands of copies of positive studies relating to off-label uses of Bextra® without also providing negative studies; distributed hundreds of thousands of 20 milligram doses of Bextra® to medical professionals such as orthopedic surgeons who do not generally prescribe for menstrual pain with the intent that the sample would be used off label; co-opted influential doctors to encourage off-labeling prescribing; provided meals and gifts to doctors who prescribed Bextra® off-label; promoted Continuing Medical Education ("CME") classes that encouraged off-label uses; rewarded high off-label prescribers with paid "preceptorships" and consultancies; disseminated print advertisements with text and imagery that communicated Bextra®'s supposed efficacy against acute pain; and encouraged sales representatives to promote off-label uses in their sales calls. Instead of marketing Bextra® safely and responsibly, DEFENDANT was driven by their narrow desire to maximize profits.

STATEMENT OF FACTS

Cox-2 Painkillers Were Developed in a Lucrative Market.

10. NSAIDs such as naproxen (Aleve®) and ibuprofen (Advil®) have been widely prescribed for many years to treat the symptoms of arthritis as well as chronic and acute pain from other causes. NSAIDs are highly effective against pain and inflammation; however, they can cause gastrointestinal ("GI") side effects, including serious adverse events such as obstructions, bleeds, and perforations. These drugs are also sold over-the-counter ("OTC") at dosages lower than prescription strength. For the most part, NSAIDs are available generically and are thus significantly cheaper than branded COX-2 drugs.

11. NSAIDs work against pain and inflammation by inhibiting enzymes known as cyclo-oxygenase or COX. There are two forms of COX enzymes: COX-1 and COX-2. COX-1 is involved in the maintenance and repair of the GI system.

12. Selective COX-2 inhibitors ("COX-2 drugs") are drugs that block COX-2 without affecting COX-1. This class of drugs was developed in the 1990s in hope of reducing pain and inflammation without blocking COX-1's beneficial effect on the GI system; however, the scientific studies of COX-2 drugs have been inconclusive regarding gastrointestinal safety.

13. The scientific rationale and justification for COX-2 drugs was safety, not efficacy. No scientifically valid clinical trial has ever found COX-2 drugs to be more effective for treatment of pain and inflammation than traditional NSAIDs.

14. There are significant concerns that COX-2 drugs as a class may increase the risk of cardiovascular ("CV") adverse events such as stroke and heart attacks.

15. In total, three COX-2 drugs have been approved for sale in the United States: Celebrex® (celecoxib), Vioxx® (rofecoxib), and Bextra® (valdecoxib). DEFENDANT began marketing Celebrex® in early 1999 and Merck followed several months later with Vioxx®. In early 2002, DEFENDANT began marketing Bextra®. Ultimately, Vioxx® was withdrawn from the market in 2004; Bextra® was withdrawn in 2005, and that same year, Celebrex® was given a "black box" warning on its label concerning CV risks associated with COX-2 drugs.

16. DEFENDANT competed vigorously with Merck for the rapidly expanding COX-2 market. DEFENDANT'S sales representatives were paid significant bonuses to get doctors to switch patients from Vioxx® to Celebrex® or Bextra®.

17. Celebrex® was disadvantaged in its competition with Vioxx® because unlike Vioxx®, Celebrex® was not initially approved for the treatment of acute pain. Although eventually Celebrex® was approved for this indication, the late approval impaired Celebrex®'s ability to compete in the acute pain market and many doctors considered Celebrex® less effective against acute pain.

Defendant Developed Bextra® to Be a "Blockbuster" Painkiller but Studies Revealed Safety Concerns.

18. DEFENDANT planned to "create the next [COX-2] blockbuster" by marketing Bextra® as a "powerful agent" for both acute and chronic pain with strength equal to that of a schedule 2 narcotic. Bextra®'s initial product profile identified acute pain, opioid sparing, and preemptive analgesia associated with the treatment of surgical pain as Bextra®'s distinguishing qualities. By focusing on these qualities, DEFENDANT sought to supplement Celebrex®'s perceived weaknesses against acute pain with Bextra®'s strength and prevent Bextra® from cannibalizing Celebrex® sales. Bextra® would primarily target young active patients with acute pain while Celebrex® would primarily target older patients with chronic pain (e.g. – pain associated with arthritis). Bextra® would compete directly against Vioxx® in the acute pain market while Celebrex® would compete primarily against traditional NSAIDs including OTC drugs, for chronic pain.

19. On November 27, 2001, the FDA approved the 10mg dose Bextra® for the treatment of pain associated with rheumatoid arthritis and osteo-arthritis and the 20 milligram dose for pain associated with primary dysmenorrhea, but expressly rejected Bextra®'s use at any dose for acute and perioperative pain and opioid sparing indications. The FDA rejected Bextra® for those uses primarily because the Coronary Artery Bypass Graft Study 035 ("CABG

I") demonstrated an excess of serious adverse events including death in association with Bextra® and Bextra®'s pro-drug, parecoxib.

20. CABG I was a randomized, double-blind comparison of two groups of patients who underwent coronary artery bypass graft surgery. One group in the study received Bextra® and parecoxib, along with narcotics, to treat perioperative pain. The other group only received narcotics (also known as the "standard of care"). DEFENDANT'S goal for CABG I was to demonstrate that Bextra® was safe and effective to treat surgical pain and reduce the incidence of narcotic related adverse events such as nausea, constipation, and somnambulence. The results of the CABG I study, however, showed that although patients given Bextra® used fewer narcotics, there was no reduction in narcotic related side effects. Further, patients given Bextra® suffered twice as many Serious Adverse Events ("SAEs") compared to patients who did not receive Bextra®.

21. To minimize the safety concerns raised by CABG I, DEFENDANT compared Bextra®'s SAE rate with observational reports outside the study and claimed that Bextra®'s SAE rate was within normal limits. This substitution of an after the fact control group data is scientifically dishonest and contrary to generally accepted scientific methods. DEFENDANT attempted to further minimize the negative results of CABG I by claiming there was a "failure of randomization" that caused weaker patients to be placed in the Bextra® test group.

22. In addition, in an attempt to frame the negative CABG I results as a fluke, on or about January 28, 2003, DEFENDANT began a second clinical trial relating to Bextra® and CABG surgery. The "CABG II" study compared three similarly sized groups: patients who received narcotics; patients who received narcotics plus Bextra®; and patients who received narcotics, Bextra®, and parecoxib.

23. DEFENDANT enrolled patients into their CABG II study without disclosing to them that their counterparts in CABG I experienced a doubling of SAEs. Rather, the increased

SAE rate was minimized and potential subjects were told that side effects in CABG I were within the expected number of side effects typically seen in CABG surgeries.

24. CABG II confirmed the risk of high dose Bextra® for post-operative pain relief: patients who received Bextra® experienced significantly more heart attacks and other cardiovascular problems compared to patients who did not receive Bextra®.

25. CABG II combined with CABG I raised significant concerns about the safety of Bextra® for all patients, even at low doses. Nonetheless, DEFENDANT continued to promote high dose Bextra® for acute pain and perioperative uses.

26. In November 2004, the FDA required DEFENDANT to disclose the negative SAE data results of both CABG studies in a revised package insert for Bextra®.

27. Nonetheless, beginning in 2001 after the FDA denial of certain indications and despite clear evidence of risks associated with high dosing of Bextra®, DEFENDANT proceeded with its original marketing plan to market Bextra® for the now FDA-disapproved indications of acute, perioperative pain and opioid sparing indications.

DEFENDANT Created and Distributed Biased Science and Unfair and Imbalanced Information.

28. As part of their illegal marketing efforts, DEFENDANT unlawfully distributed and discussed many studies that described off-label indications. Notwithstanding official and legal admonitions against using off-label studies for marketing efforts, DEFENDANT disseminated hundreds of thousands of clinical studies that supported using Bextra® for acute and perioperative pain and opioid sparing use for the purpose of promoting Bextra® for off-label use. Additionally, DEFENDANT did not comply with requirements to balance favorable information by the equal distribution of relevant unfavorable studies, and DEFENDANT did not disclose the negative results from the CABG studies or the FDA's rejection of Bextra® for acute, perioperative pain and opioid sparing indications.

29. DEFENDANT disseminated hundreds of thousands of copies of an article entitled "Valdecoxib, a COX-2 -- Specific Inhibitor, Is an Efficacious Opioid-Sparing Analgesic in Patients Undergoing Hip Arthroplasty," by Frederic Camu, M.D. ("Camu"), which was published in the American Journal of Therapeutics in 2002. DEFENDANT distributed the Camu study to orthopedic surgeons, anesthesiologists, and other surgical specialists knowing these specialists would be prescribing Bextra® off-label for perioperative pain and opioid sparing.

30. DEFENDANT distributed hundreds of thousands of copies of an article entitled "Valdecoxib Does Not Impair Platelet Function," by Philip T. Leese, M.D. ("Leese"), which was published in the Journal of Emergency Medicine in 2002. DEFENDANT distributed the Leese article as proof that Bextra® could be used for perioperative pain without causing increased bleeding after surgery.

31. DEFENDANT also distributed hundreds of thousands of copies of an article entitled "The Analgesic Efficacy of Valdecoxib Versus Oxycodone/Acetaminophen after Oral Surgery," by Stephen E. Daniels, D.O. ("Daniels"), which was published in the Journal of the American Dental Association (JADA) in 2002. DEFENDANT commissioned the Daniels study as part of a strategy to create and disseminate medical studies that supported prescribing Bextra® for perioperative pain and opioid sparing use. The Daniels study was not conducted by a mainstream academic organization; rather DEFENDANT hired SCIREX, a contract research organization owned by a large advertising company, and hired by DEFENDANT. The Daniels study was designed to produce misleading study results because it compared Bextra® to a single dose of a medicine that is usually given in multiple doses. Although the Daniels study was published by Journal of the American Dental Association ("JADA"), one of the journal's editors later explained that they were not told that Bextra® was disapproved for the treatment of acute pain. Had JADA's editors known the truth, the Daniels study would not have been published.

32. DEFENDANT widely disseminated the Camu, Leese, and Daniels studies to its sales representatives, urged them to distribute the articles on their sales calls, and provided them with discussion notes that enabled sales representatives to discuss these off-label studies during their sales calls. Although the materials DEFENDANT produced for sales representatives often contained a "do not detail" advisement cautioning against any discussion of the studies during sales calls, the warning was illusory and widely ignored.

33. DEFENDANT also attempted to hire influential medical professionals to present the results of these studies in order to give a false appearance of reliability to DEFENDANT own self-generated and financed study results.

34. In 2003, the Journal of Thoracic and Cardiac Surgery published CABG I as an article entitled "Efficacy and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in Patients Undergoing Coronary Artery Bypass Surgery" by Elisabeth Ott, M.D. ("Ott"). This article raised important concerns about the safety of high dose Bextra® for treatment of acute and perioperative pain and for opioid sparing uses and suggested the need for a comprehensive evaluation of a large-scale trial before using Bextra® to treat vulnerable patients. DEFENDANT promoted Bextra® for acute and perioperative pain and opioid sparing uses yet failed to disclose this article to the medical community and did not approve it for distribution by sales representatives.

35. DEFENDANT also promoted off-label uses of Bextra® in medical inquiry response letters. FDA regulations permit drug manufacturers to provide off-label information in response to an unsolicited inquiry from a medical professional so long as the responsive material contains balanced information and is not promotional. Similar to its strategy of distributing only favorable off-label medical articles, DEFENDANT disclosed only favorable data about acute and perioperative pain and opioid sparing indications in their responses to medical inquiries and omitted negative CABG I results and the FDA denials.

Defendant Improperly Distributed Free Samples of Bextra® with the Intent to Have Samples Used for Off-label Indications.

36. DEFENDANT promoted off-label use of Bextra® to treat acute and perioperative pain and opioid sparing by giving hundreds of thousands of 20 milligram Bextra® samples to surgeons, anesthesiologists, and other surgical and pain specialists who do not customarily treat severe menstrual cramps, but who do treat acute and perioperative pain. DEFENDANT intended for medical specialists to use the 20 milligram samples to treat acute and perioperative pain and for opioid sparing use but failed to disclose the negative results from the CABG I and CABG II studies and failed to disclose that FDA had rejected these indications due to concerns about their safety.

Defendant Employed an Enormous Sales Staff to Market Bextra® for Off-Label Uses.

37. DEFENDANT relied heavily on their enormous sales staff to market Bextra® for off-label and FDA-denied indications. DEFENDANT produced deceptive sales messages that promoted Bextra® for acute and perioperative pain and opioid sparing and trained sales representatives to effectively use this messaging to increase off-label sales. Sales representatives promoted Bextra®'s off-label indications to health care providers and were encouraged to detail health care providers extensively about these FDA-denied indications.

38. Sales managers carefully tracked sales representatives' success in conveying DEFENDANT'S messages by monitoring electronic call notes submitted by sales representatives and accompanying them on sales calls. DEFENDANT also knew that sales representatives were detailing Bextra® for acute and perioperative pain based on surveys conducted by consultants hired by DEFENDANT to track and monitor prescribing information.

39. DEFENDANT sought to increase Bextra® sales for acute and perioperative pain and opioid sparing by aggressively targeting surgeons, surgery centers, and hospitals to get Bextra® placed on "standing orders" and "protocols" for these indications. Surgery centers and hospitals rely on standing orders and protocols for analgesic dosing regimes associated with

perioperative pain. DEFENDANT'S success in placing Bextra® on surgical standing orders directly increased Bextra® sales, served as a powerful tool for promoting Bextra® to other doctors and hospitals, and increased the likelihood that surgical patients would remain on Bextra® to treat chronic pain conditions after surgery.

40. DEFENDANT also obtained examples of surgical protocols and standing orders that included analgesic dosing regimes for Bextra® and disseminated these samples to sales representatives. DEFENDANT held contests and rewarded sales representatives with recognition, accolades, and cash equivalent prizes for obtaining high volume standing order sales.

Defendant Engaged in Off-Label Advertising to Consumers and Providers Using the Pretense of Education.

41. Physician education programs were another integral part of DEFENDANT'S scheme to promote Bextra® for acute and perioperative pain and opioid sparing indications. DEFENDANT hired surgeons, anesthesiologists, and other pain specialists to conduct physician education programs ranging from informal luncheon presentations to Continuing Medical Education programs. DEFENDANT knew off-label topics would be discussed at these programs and provided speakers with presentation slides containing favorable off-label data and information about Bextra®.

42. DEFENDANT'S market research indicated that more patients suffered from non-arthritis pain than arthritis pain. To reach beyond the arthritis pain market, DEFENDANT developed and widely used marketing materials that promoted Bextra® to treat acute pain caused by sprains, strains, tendonitis, and bursitis. To avoid the appearance of off-label marketing, however, DEFENDANT'S sales messages used euphemisms for acute pain such as "tough pain," "flare pain," "acute pain condition," and "episodic pain" and visual imagery that evoked strong and powerful pain relief.

43. DEFENDANT also used patient-type marketing to enhance its acute pain message for Bextra®. Throughout its marketing campaign, DEFENDANT consistently targeted the young active "weekend warrior" patient with tough episodic pain for Bextra®. In contrast, and to distinguish the target market for Celebrex®, DEFENDANT promoted Celebrex® for the older patient suffering from chronic pain.

44. DEFENDANT'S marketing surveys, focus groups, and feedback from its field sales force confirmed that doctors consistently perceived Bextra®'s strong powerful pain relief messaging as targeting the acute pain market.

45. DEFENDANT also promoted its "weekend warrior" imagery in its direct-to-consumer advertising. DEFENDANT distributed hundreds of thousands of copies of a self-published periodical called Perform Magazine that contained multiple images and messages promoting Bextra®'s strong powerful pain relief. Perform Magazine was sent to subscribers of People magazine and widely distributed in patient waiting rooms.

46. DEFENDANT invited surgeons and other pain specialists who were likely to prescribe Bextra® off-label to so-called "consultant" meetings. Although DEFENDANT claimed these meetings were not promotional, they conducted return on investment analysis on some attendees to determine whether there was a sufficient increase in prescriptions to financially justify the costs of the meetings.

Defendant Gave Improper Inducements, Payments, and Gifts to Physicians.

47. To illegally promote Bextra® off-label from within the medical community, DEFENDANT also hired surgeons, podiatrists, anesthesiologists, and other specialties to conduct Bextra® off-label dinner talks and round tables. DEFENDANT sought out and developed physician speakers who were high prescribers of Bextra® and supported its off-label use – these health care providers were then paid to give lunch or dinner talks relating to off-label use of Bextra®.

48. DEFENDANT maintained a stable of recommended and paid physician-speakers that sales staff could use for off-label Bextra® dinner talks. Sales staff often worked with physicians on their presentations, and encouraged health care providers to talk about off-label uses, even though this practice is prohibited. Talks were conducted at expensive top flight restaurants. DEFENDANT conducted analyses on physicians to confirm that their prescribing behavior increased after speaking or after attending dinner programs.

49. DEFENDANT rewarded doctors who were high off-label prescribers of Bextra® with "preceptorships" in which the doctor was paid up to $500 to allow Bextra® sales representatives to follow him or her around on clinical rounds and attend surgeries.

50. DEFENDANT used preceptorships to gain access to doctors who otherwise would not allow sales representatives to visit their office. During the preceptorship, the sales representatives were encouraged to discuss using Bextra® to treat acute and perioperative pain.

51. DEFENDANT also cultivated off-label Bextra® prescribers by rewarding certain prescribers with clinical research grants and contracts.

52. In addition to gifts to prescribers, DEFENDANT provided grants to certain medical centers and hospitals and leveraged the resultant "goodwill" to promote off-label use of Bextra®.

To Enhance Its Unlawful Marketing Campaign, Defendant Concealed and Misrepresented Bextra®'s Safety and Risks.

53. As DEFENDANT marketed Bextra® to more health care providers, for more patients, and for a wider assortment of illnesses and pain types, DEFENDANT consistently avoided, minimized, and failed to disclose material health and safety risks. DEFENDANT deceptively marketed Bextra® as the most powerful non-narcotic medication without clinically reliable evidence for such a claim, and while omitting important information that showed Bextra® was no better and potentially more dangerous than traditional NSAIDs in treating pain.

54. DEFENDANT'S decision to minimize or fail to disclose the results from CABG I, the study which was the basis for the FDA's denial of Bextra® for acute pain prevented doctors from fully educating themselves about Bextra® and created a dangerous situation where health care providers were prescribing a drug without knowing all of the risks.

55. DEFENDANT also deceptively promoted Bextra®'s gastrointestinal safety in brochures mailed directly to consumers. Although Bextra®'s FDA approval label cautioned that Bextra® could cause serious and life-threatening gastrointestinal side effects, including bleeding in the stomach and intestines, DEFENDANT'S direct to consumer brochures misrepresented that, for patients who take Bextra®, the "stomach stays protected." DEFENDANT ran a similarly deceptive advertisement in Perform Magazine.

56. DEFENDANT'S sales staff told health care providers that Bextra® was safe and effective, without affirmatively explaining side effects or adverse events. DEFENDANT'S sales executives specifically told sales staff not to initiate discussion of Bextra® safety.

57. DEFENDANT also attempted to confuse health care providers to believe positive Celebrex® data also applied to Bextra®. DEFENDANT promoted both Bextra® and Celebrex® at the same time and their marketing materials and representations intentionally conflated research data so that Celebrex® studies were used to explain the safety and efficacy of Bextra®, even though Celebrex® was a different drug and approved for different indications.

DEFENDANT'S Unlawful Marketing Scheme Had a Powerful Effect.

58. DEFENDANT'S promotional scheme for Bextra® was highly successful. Total Bextra® sales approached four billion dollars, most of which were for acute and perioperative pain and opioid sparing indications and not for the 10 milligram dose treatment of pain associated with rheumatoid arthritis and osteo-arthritis and the 20 milligram dose treatment for pain associated with primary dysmenorrhea.

CAUSE OF ACTION

59. The Arizona Consumer Protection Act, A.R.S. § 44-1522(A) states: The act, use, or employment by any person of any deception, deceptive act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived, or damaged thereby, is declared to be an unlawful practice.

60. The acts and practices set out above constitute consumer fraud under § A.R.S. 44-1521 *et seq.*

61. At all times DEFENDANT acted wilfully acted in violation of A.R.S. § 44-1531.

PRAYER FOR RELIEF

The State of Arizona respectfully request that a judgment and order be entered that:

1. Permanently enjoins DEFENDANT from engaging in the misleading and deceptive practices as defined in the Arizona Consumer Fraud Act, A.R.S. § 44-1521 *et seq.*

2. Direct DEFENDANT to pay civil penalties for each willful violation pursuant A.R.S. § 44-1522 and A.R.S. § 44-1531.

3. Direct DEFENDANT to pay the State's costs including attorney's fees pursuant to A.R.S. § 44-1534.

4. Grant all other Relief as the Court deems appropriate.

DATED this 22nd day of October, 2008.

TERRY GODDARD
Attorney General

By: Noreen Matts
NOREEN R. MATTS
Assistant Attorney General