No. 365PA09 **FIFTH DISTRICT**

SUPREME COURT OF NORTH CAROLINA

****

STATE OF NORTH CAROLINA	**)**	
	)	
V.	**)**	**From New Hanover County**
	)	**No. COA08-978**
JIMMY WAYLON WARD	**)**	

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BRIEF OF *AMICUS CURIAE* (NORTH CAROLINA ADVOCATES FOR JUSTICE)

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No. 365PA09 **FIFTH DISTRICT**

SUPREME COURT OF NORTH CAROLINA

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STATE OF NORTH CAROLINA	**)**	
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BRIEF OF *AMICUS CURIAE* (NORTH CAROLINA ADVOCATES FOR JUSTICE)

****

ISSUE PRESENTED

WHETHER THE COURT OF APPEALS CORRECTLY CONCLUDED THE ADMISSION OF AN EXPERT OPINION IDENTIFYING PILLS AS CONTROLLED SUBSTANCES BASED SOLELY ON VISUAL EXAMINATION CONSTITUTED REVERSIBLE ERROR?

STATEMENT OF THE CASE

This *amicus curiae* brief incorporates by reference the Statement of the Case in the Defendant-Appellee's New Brief.

STATEMENT OF THE FACTS

This *amicus curiae* brief incorporates by reference the Statement of the Facts in the Defendant-Appellee's New Brief.

ARGUMENT

THE COURT OF APPEALS CORRECTLY CONCLUDED THE ADMISSION OF AN EXPERT OPINION IDENTIFYING PILLS AS CONTROLLED SUBSTANCES BASED SOLELY ON VISUAL EXAMINATION CONSTITUTED REVERSIBLE ERROR.

This Court has already ruled that expert testimony is required to identify a controlled substance. *State v. Llamas-Hernandez*, 363 N.C. 8, 673 S.E.2d 658 (2009) (per curiam). This Court should further hold that visual identification is not a sufficiently reliable method of proof for such expert testimony.

North Carolina has a "three-step inquiry for evaluating the admissibility of expert testimony: (1) Is the expert's proffered method of proof sufficiently reliable as an area for expert testimony? (2) Is the witness testifying at trial qualified as an expert in that area of testimony? (3) Is the expert's testimony relevant?" *Howerton v. Arai Helmet, Ltd.*, 358 N.C. 440, 458, 597 S.E.2d 674, 686 (2004) (citing *State v. Goode*, 341 N.C. 513, 527-29, 461 S.E.2d 631, 639-41 (1995). In this case, the

State failed to meet the burden of the first step. State Bureau of Investigation Special Agent Irvin Lee Allcox testified as an expert in the field of chemical analysis of drugs and forensic chemistry. He purported to identify certain seized tablets based on a visual examination of their size, shape, color, and markings. This examination was not a sufficiently reliable method of proof for expert testimony.

Visual examination is insufficient to identify a controlled substance. Visual examination is insufficient whether the substance is in pill, liquid, powdered, crystallized, organic, or any other form. Visual examination is insufficient for whatever the substance is suspected of being. The concept that nothing else looks like any particular controlled substance is a false assumption.

There is nothing unique about the visual appearance of cocaine, whether in powder or crack form. "[T]he proliferation of counterfeit or look-alike substances is so substantial as to render the identification of suspected cocaine through sight alone a tenuous proposition at best." *Robinson v. State*, 348 Md. 104, 126, 702 A.2d 741, 751 (1997).

In *State v. Williams*, 164 N.C. App. 638, 596 S.E.2d 313 (2004), the defendant was convicted of possession with intent to sell counterfeit cocaine and possession with intent to deliver counterfeit cocaine. Based on visual identification as well as other circumstantial evidence, at least two trained and experienced law enforcement officers believed that the substance that the defendant possessed and

was selling was crack cocaine. Also based on visual identification, the State's expert forensic chemist believed the substance to be crack cocaine. Defendant-Appellant's Brief, *State v. Williams*, No. COA03-503, at 6; State-Appellee's Brief, *State v. Williams*, No. CO3-503, at 13.[1] (See Appendix) It was only subsequent chemical analysis that revealed the substance to in fact be Goody's Headache Powder. Appellant's Brief, *State v. Williams*, No. COA03-503, at 6, 11; State-Appellee's Brief, *State v. Williams*, No. CO3-503, at 12-13. (See Appendix)

In *In re Timothy F.*, 343 Md. 371, 681 A.2d 501 (1996), pieces and crumbs of what might have been dried milk or soap chips resembled crack cocaine. Only forensic testing "confirmed that the substance was not crack cocaine or any other" controlled substance. *Id*. at 374, 681 A.2d at 503.

In 2007, authorities began to complain that a mint on the market had the visual characteristics and packaging of crack cocaine, powdered cocaine, and heroin. "Being in narcotics the majority of my career, I thought it was the real stuff," said [Philadelphia Police Chief Inspector William] Blackburn. Jill Porter,

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[1] The analysis by and opinion of the forensic chemist in *State v. Williams* is set out in the briefings by both parties but not in the Court of Appeals ruling. North Carolina appellate courts may take judicial notice of their own records including briefs. *Swain v. Creasman*, 260 N.C. 163, 164, 132 S.E.2d 304, 405 (1963); see also, *State v. Ward*, 338 N.C. 64, 127, 449 S.E.2d 709 (1994), *cert. denied*, 514 U.S. 1134, 131 L. Ed. 2d 1013 (1995) (judicial notice taken of filings in co-defendant's case); *Alford v. Shaw*, 327 N.C. 526, 541, 398 S.E.2d 445 (1990) (judicial notice taken of briefs filed in appeal of earlier judgment). Amicus respectfully requests that this Court take judicial notice of the briefings by the parties in *State v. Williams*, No. COA03-503.

Mint or drug: Is Hershey's cracked? PHILA. DAILY NEWS, Nov. 30, 2007, at A1. (See Appendix) With authorities unable to visually distinguish the candy from crack cocaine, powdered cocaine, or heroin, Hershey's stopped manufacturing the mints. Josh Fineman and Tim Catts, *Hershey to Pull Icebreaker Mints That Resemble Drugs*, http://www.bloomberg.com/apps/news?pid=conewsstory&refer=conews&tkr=HSY:US&sid=aUHVMRwPSkvk (last visited 7 Dec. 2009; see Appendix).

Other candies continue to cause similar problems for experienced and trained law enforcement officers. Currently, the Kissimmee Police Department in Florida is being sued by a man who spent three months in jail because an officer visually identified his breath mints as crack cocaine. He was not released until subsequent laboratory chemical analysis revealed the truth. *Mints thought to be drugs land man in jail*, http://www.abcactionnews.com/news/local/story/Mints-thought-to-be-drugs-land-man-in-jail/81-q9OZI2Uyr5bGp0q5qaA.cspx (last visited 20 Dec. 2009; see Appendix).

There is nothing unique about the visual appearance of phencyclidine (PCP). In *Allen v. State*, 91 Md. App. 775, 605 A.2d 994 (1992), an officer visually identified the substance in a jar as PCP. It was parsley. *Id*. at 778, 605 A.2d at 996.

There is nothing unique about the visual appearance of marijuana. In *State v. Seagull*, 95 Wash. 2d 898, 907, 632 P.2d 44, 50 (1981), an "officer who had

observed marijuana both in plant and crushed leaf form for the past 8 years," visually identified tomato plants in a greenhouse as marijuana plants.

In *State v. Carter*, 616 Or. 6, 848 P.2d 599 (1993), a law enforcement officer visually identified the color and stem of a common green houseplant as consistent with marijuana. The officer was "a trained expert in the visual identification of marijuana." *Id*. at 10, 848 P.2d at 601. The officer's training, along with other circumstantial evidence resulted in a search warrant being issued. The Oregon Supreme Court ruled that the officer's expert visual identification "did not establish statutorily required probable cause to issue a warrant." *Id*. at 14, 848 P.2d at 603.

In *Waltman v. Payne*, 535 F.3d 342, 344 (5th Cir. 2008), several officers, based on visual identification as well as other circumstantial evidence, determined that plants in a field were marijuana. 500 plants were seized. The officers had "received advanced training and experience identifying and eradicating marijuana." *Id*. at 347. Subsequent analysis showed the plants to be the legal kenaf. "Most of the officers were confident that the kenaf was marijuana, and even the officers who were not convinced thought that it was likely." *Id*. The Fifth Circuit noted that "certain strains of kenaf are virtually indistinguishable from marijuana by visual inspection." *Id*. at 344.

Visual identification is no more reliable for pills. The State dismisses the potential existence of counterfeit pharmaceuticals. In reality, counterfeit pharmaceuticals are a growing, underreported problem. *See* Robert Cockburn et al., *The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers*, PLoS Med 2005 April, http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0020100 (estimate of prevalence of counterfeit drugs; see Appendix). After noting a sharp increase in counterfeit drug investigations, the U.S. Federal Drug Administration ("FDA") formed a Counterfeit Drug Task Force in July 2003 as part of a greater initiative to combat counterfeit drugs in the American supply chain. The FDA is taking seriously the problem that counterfeit pharmaceuticals are packaged and designed to look like their legitimate counterparts.

Visual identification is not a reliable method for conclusively identifying a controlled substance in pill form. The reality is that "counterfeiters have gained access to sophisticated technologies." *FDA Initiative to Combat Counterfeit Drugs*, http://www.fda.gov/Drugs/DrugSafety/ucm180899.htm (last visited 18 Dec. 2009; see Appendix). For example, the Santa Rosa Police Department in California identified seized tablets as Methylin (methylphenidate) by visually comparing the tablets to the Drug Identification Bible publication. Only subsequent laboratory analysis by the California Bureau of Forensic Services Laboratory indicated there

was no methylphenidate present in the tablets. U.S. Drug Enforcement Admin. Office of Forensic Sciences, *Microgram Bulletin*, Vol. XXXVII, No. 4, April 2004, p. 64. (See Appendix)

These examples, and others like them, demonstrate the false presumption that no other substance looks like any particular controlled substance. This Court should uphold the unanimous opinion of the Court of Appeals in *State v. Ward*, ___ N.C. App ___, 681 S.E.2d 354 (2009), should overrule *State v. Freeman*, 185 N.C. App. 408, 648 S.E.2d 876 (2007), and should expand upon its adoption of Judge Steelman's dissent in *State v. Llamas-Hernandez*, 189 N.C. App. 640, 659 S.E.2d 79 (2008). This Court should make it clear that expert testimony is required to establish a substance is in fact a controlled substance, no matter what the substance is, and that visual identification is not a reliable method to conclusively prove a substance is a controlled substance. Looking pictures up in a book is no substitute for chemical analysis in an accredited laboratory.

CONCLUSION

For the foregoing reasons, this Court should affirm the decision of the Court of Appeals and expressly hold that visual identification is not a reliable method to prove a substance is a controlled substance.

Respectfully submitted this the 23rd day of December 2009.

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CERTIFICATE OF COMPLIANCE WITH N.C.R. APP. P. 28(j)(2)(B)

The undersigned hereby certifies that this Brief of *Amicus Curiae* North Carolina Advocates for Justice is in compliance with Rule 28(j)(2)(B) of the North Carolina Rules of Appellate Procedure in that it is printed in 14 point Times New Roman font and contains no more than 3,750 words in the body of the Brief, footnotes and citations included, as indicated by the word-processing program used to prepare the Brief.

By electronic submission
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CERTIFICATE OF FILING AND SERVICE

The undersigned hereby certifies that the original Brief of *Amicus Curiae* North Carolina Advocates for Justice has been filed pursuant to Rule 26(a)(2) of the North Carolina Rules of Appellate Procedure by electronic means with the Clerk of the Supreme Court of North Carolina.

The undersigned further certifies that the foregoing Brief of *Amicus Curiae* North Carolina Advocates for Justice has been served pursuant to Rule 26(c) of the North Carolina Rules of Appellate Procedure by electronic means upon the following parties:

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NO. COA 03-503 DISTRICT TEN

NORTH CAROLINA COURT OF APPEALS
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STATE OF NORTH CAROLINA	)	
	)	
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	)	
MICHAEL CORNELIUS WILLIAMS	)	

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DEFENDANT-APPELLANT'S BRIEF

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handcuffs. Tp. 134 Ln. 9-23.

Officer Christopher Joseph Robb of the Raleigh Police Department testified that he was riding with Rosa. Tp. 163 Ln. 14. They had received a description of the suspect and observed two persons wearing toboggans with New York on them. Tpp. 165-7 Ln. 1-24. The second person was detained further down the block and a picture apparently was taken of him. Tpp. 167-8 Ln. 25-5. The defendant was released after Robb was informed the suspect had been detained. Tp. 169 Ln. 2-16. Once informed that the other suspect was not involved in the instant offense, Robb and Rosa located the defendant sitting on a porch on Freeman Street. Tpp. 169-70 Ln. 18-12. Several other people were in the yard and on the porch. The defendant was not wearing a toboggan or jacket; these items were located on the porch by Rosa. Tpp. 171-2 Ln. 1-12. Rosa informed Robb that he observed the defendant drop what appeared to be crack cocaine; Robb, however, did not observe this action. Tp. 173 Ln. 2-10.

Amy Bommer, a forensic drug chemist with the City County Bureau of Identification [CCBI] was qualified as an expert in forensic chemistry. Tp. 186 Ln. 1-17. Bommer testified that she analyzed the contents of State's Exhibits 1 and 1A and concluded that they were not controlled substances. Bommer indicated that the substances did appear to look like crack cocaine. Tp. 192 Ln. 1-11.

person also was wearing a toboggan with a New York Yankees symbol on it. Tp. 111 Ln. 12-21.

Rosa testified on cross-examination that the defendant had been standing around the porch with four to five other people when they were ordered to sit down. The defendant wound up sitting next to the chair with the jacket and toboggan. Tpp. 145-7 Ln. 7-14. Rosa did not recall seeing brown boots on the porch, tp. 153 ln. 22-25, nor did he recall if the defendant was wearing boots when he was first detained. Tp. 154 Ln. 1-23.

Robb testified on cross-examination that he could not remember if the defendant was wearing brown boots during the first encounter. Tpp. 177-8 Ln. 22-22. Robb was standing about one foot behind the defendant when he was patted down the second time. Robb ordered the defendant to put his left hand on his head, but did not see anything drop out of the defendant's hand. Tpp. 179-80 Ln. 13-18. Robb found nothing through a frisk of the defendant. Tp. 182 Ln. 3-8.

Bommer testified on cross-examination that State's Exhibits 1 and 1A consisted of Goody's headache powder. Tpp. 192-3 Ln. 19-3. She was not asked to examine any currency to determine the presence of Goody's headache powder. Tp. 194 Ln. 12-16.

The habitual felon phase of the trial commenced after the jury convicted the defendant of possession with intent to sell a counterfeit controlled substance and possession with intent to

NO. COA03-503 10th JUDICIAL DISTRICT

NORTH CAROLINA COURT OF APPEALS

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STATE OF NORTH CAROLINA, State-Appellee,	)	
v.	)	From Wake County Nos. 01CRS116511, 02CRS9478
MICHAEL CORNELIUS WILLIAMS, Defendant-Appellant.	)	

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STATE-APPELLEE'S BRIEF

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was within arm's reach of Defendant on the porch, along with a Navy blue jacket. (T pp. 138-139)

Officer Robb testified that when he and Rosa arrived at Martin and Freeman Streets less than a minute after the radio description was given, they detained Defendant for the first time. He matched the description and was wearing a toboggan with New York on it, along with blue jeans and a blue jacket. (T pp. 165-166, 178) After a brief period of time, a detective mistakenly said to release Defendant because he was the wrong suspect. (T p. 169) After being told moments later to find Defendant again and detain him, the officers walked down to 308 Freeman Street where they saw Defendant sitting in a chair on a porch of a residence. Defendant had changed his appearance: he was no longer wearing the hat and had taken off his jacket. Both items were within arm's reach of Defendant on the porch, according to Robb. Robb remembers Defendant as having knotty hair. (T pp. 170-172)

Amy Bommer, a forensic drug chemist with the City County Bureau of Identification, CCBI, was qualified as an expert in the area of forensic chemistry. (T p. 186) Bommer testified that crack cocaine is an off-white hard substance, usually sold in small little rocks. (T p. 189) Bommer testified that she performed chemical tests on the contents of State's Exhibits 1 and 1A, which were received into evidence, and both the contents

were found not to be cocaine or any other type of controlled substance. However, when she first looked at them, they appeared to be crack cocaine. (T p. 192) Bommer determined that the contents of both exhibits were Goody's Headache Power. (T p. 193)

ARGUMENT

I. THE TRIAL COURT DID NOT ERR BY PERMITTING TESTIMONY CHARACTERIZING THE CONDUCT AND FREQUENCY OF DRUG SALES IN THE FREEMAN AND MARTIN STREET AREAS OF RALEIGH, BUT EVEN IF THE COURT ERRED, IT WAS HARMLESS ERROR.

(Assignments of Error Nos. 1 and 2, Rp. 51)

Defendant alleges the trial court erred when it allowed into evidence testimony from Campos and Hobby concerning the reputation of the neighborhood where Defendant was arrested as being an open air drug market, inter alia. But it is clear from case law that such reputation evidence is admissible under certain circumstances, such as those that existed in the case sub judice. But even if it were error, such error was harmless under the law.

Evidence concerning the "drug use" reputation of a place that tends to show the intent of a defendant charged with feloniously and intentionally acquiring possession of a controlled substance is admissible in a criminal prosecution. State v. Stevenson, 136 N.C. App. 235, 240-241, 523 S.E.2d 734, 737 (1999); The motive of a Defendant is a material fact to be considered, though the prosecution is not required to prove it. State v. Riddick, 315 N.C. 749, 758, 340 S.E.2d 55, 60 (1986).

Mint or drug: Is Hershey's cracked?
Jill Porter
Philadelphia Daily News
11/30/07

FAMILY COURT Judge Lori Dumas Brooks wanted to make sure she wasn't overreacting.

So she held the small blue packet of powdered substance in her palm and showed it around at work yesterday.

Everyone asked the same thing:

What was she doing with crack cocaine?

"I thought she confiscated it in the courtroom," said Administrative Judge Kevin Dougherty.

No one could believe what the tiny pouch actually was: a new breath mint made by - get this - Hershey's.

Ice Breakers Pacs, which hit the stores this month, are dissolvable pouches in blue or orange that look uncannily like tiny heat-sealed bags of cocaine, crack, heroin or any other powdered drug.

The Pacs, filled with powdered mint and sweetener, are meant to dissolve on the tongue like breath strips.

They're even packaged in a plastic slide-top case similar to the magnetic key cases drug dealers use to hide their wares under cars.

"I could not believe it," Judge Dumas Brooks said yesterday.

"Who in the world thought of that, and how did it get approved?"

The pouches are so realistic, they even fooled Philadelphia Police Chief Inspector William Blackburn.

"Being in narcotics the majority of my career, I thought it was the real stuff," said Blackburn.

"It's a disgrace to see a company selling a product like this and basically glorifying the drug trade. The best word to describe it is despicable."

The best word to describe Hershey's is . . . clueless.

"It's not intended to simulate anything," corporate spokesman Kirk Seville told me yesterday, refusing to acknowledge the similarities between the candy and street drugs.

"We have a longstanding commitment to consumer safety, product quality and responsible

packaging," he said, adding that the Pacs are "clearly labeled."

"The dissolvable pouch is what makes the product innovative and unique. The overwhelming feedback from consumers is they love the product."

Maybe Hershey's should have had Linda Wagner in one of its focus groups.

Wagner is a 10-year veteran of the Police Department who switched to narcotics three years ago for personal reasons: Her teenage daughter died of a heroin overdose in 2001.

When Blackburn showed her the mint packets yesterday, Wagner was near tears.

"I was shocked," she said.

"Hershey's is totally irresponsible for marketing this product."

When Officer Regina Missouri saw them, she immediately conjured up the potentially deadly scenarios the look-alike pouches could create.

What if children use them and subsequently stumble upon and ingest a real bag of drugs, thinking they're mints, she said?

What if a drug dealer mixed some in with real street drugs and sold them to an unsuspecting buyer - who retaliated with a spray of bullets?

What if a teenager took them to school? Even though each pouch has a small Ice Breakers logo on it, how would a street-naive teacher differentiate it from drug packets, which are also sometimes labeled by their distributors?

"This is unheard of; it's an insult," said Missouri, a grandmother of three young children.

She brought the packets to the attention of her commanding officer in the Employee Assistance Program, Capt. Thomas Collier, who brought it to Blackburn's attention.

Officer Tracy Brooks, Missouri's colleague in the EAP, brought some home to show his wife, Judge Dumas Brooks.

And the judge imagined another scenario: the undermining of drug busts made on visual observation of money changing hands for colored packets of powder.

"This potentially could give them a legal out," said Dumas Brooks.

"It's terrible. It's terrible."

My jaw dropped, too, when I saw the Pacs. And everyone I showed them to thought they were street drugs.

Is Hershey's trying a new edgy and urban marketing tactic? Are the candy-makers brain-dead from too much chocolate?

It's hard to imagine a company so isolated that it doesn't recognize the similarities between its "newest refreshment innovation" and the powdered junk that's for sale on the streets.

Company founder Milton Hershey - who devoted his fortune to saving children - must be rolling in his grave.

Clearly the company needs to take this product off the shelves.

"I think some strong community groups, groups with parents that have lost a loved one should unite together and petition this company and demand that this product be taken off the market," Chief Inspector Blackburn said.

Officer Wagner plans to do her part.

"I'm going to contact Hershey and hopefully I'm going to get a meeting," she said.

"I'm going to bring my daughter's picture, and let them see what drugs can do."

(http://www.philly.com/dailynews/top_story/20071130_Jill_Porter___Mint_or_drug__Is_Hersheys_c racked_.html)

Bloomberg.com

Hershey to Pull Ice Breaker Mints That Resemble Drugs (Update1)

By Josh Fineman and Tim Catts

Jan. 24 (Bloomberg) -- **Hershey Co.**, the largest U.S. candy maker, will stop making Ice Breakers Pacs mints after law enforcement officials said the candy may be mistaken for heroin or cocaine.

``Some community and law enforcement leaders have expressed concern about the shape of the pouch-and-xylitol form and the possibility that it could be mistaken for illicit items,'' Hershey Chief Executive Officer **David West** said on a conference call with analysts and investors today. ``We are sensitive to these viewpoints and thus have made the decision that we will no longer manufacture Ice Breakers Pacs.''

Ice Breakers Pacs are breath strips in a pouch filled with xylitol powder. The Hershey, Pennsylvania-based company introduced it in limited quantities late in the fourth quarter. The mints' resemblance to illegal drugs prompted Philadelphia's city council to adopt a resolution in December urging the company to ``repackage the product in a more responsible manner.''

The candy resembles illegal drugs enough that someone might mistakenly be arrested for possessing it, said Chief Inspector William Blackburn, who leads the Philadelphia Police Department's narcotics division.

``It looks more like the packaging material of heroin, but cocaine too,'' Blackburn said. No one has been arrested yet for possessing the mints, he said.

Hershey fell 71 cents, or 2 percent, to $35.68 at 4:05 p.m. in New York Stock Exchange composite **trading**. The shares dropped 7.6 percent this year through yesterday.

The company said today that fourth-quarter profit plunged 65 percent and forecast an unexpected drop in 2008 earnings, sending the shares lower.

To contact the reporter on this story: **Josh Fineman** in New York at **jfineman@bloomberg.net**; **Tim Catts** in New York at **tcatts@bloomberg.net**

Last Updated: January 24, 2008 16:38 EST

Mints thought to be drugs land man in jail

Reported by: Brandon Moseley
Email: bmoseley@abcactionnews.com
Last Update: 8/18 7:38 am

KISSIMMEE, FL -- A Central Florida man is suing the city of Kissimmee after being thrown in jail over a very costly misunderstanding.

Donald May had breath mints in his mouth during a traffic stop for an expired tag last year.

However, the officer that pulled May over thought the mints in his mouth were actually crack.

The officer claims he field-tested the evidence and results came back positive for drugs.

May was arrested and claims he wasn't allowed out of jail until tests proved the mints were not drugs.

During the three months he was behind bars, Kissimmee police had May's car towed and auctioned it off.

May was also evicted from his apartment and lost his job.

Now May is suing the city for false arrest and false imprisonment. He also wants compensation for his lost job and apartment.

Open access, freely available online

Policy Forum

The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers

Robert Cockburn☯*, Paul N. Newton☯, E. Kyerematen Agyarko, Dora Akunyili, Nicholas J. White

Introduction

The production of substandard and fake drugs is a vast and underreported problem, particularly affecting poorer countries. It is an important cause of unnecessary morbidity, mortality, and loss of public confidence in medicines and health structures. The prevalence of counterfeit drugs appears to be rising (see "The Scale of the Problem") and has not been opposed by close cooperation between drug companies, governments, or international organizations concerned with trade, health, customs and excise, and counterfeiting.

In this article we suggest that many pharmaceutical companies and governments are reluctant to publicize the problem to health staff and the public, apparently motivated by the belief that the publicity will harm the sales of brand-name products in a fiercely competitive business. Publicly, at least, several industry sources say the justification for secrecy is to avoid any alarm that could prevent patients taking their genuine medicines. We argue that this secrecy, and the subsequent lack of public health warnings, is harming patients and that it is also not in the long-term interests of the legitimate pharmaceutical industry. We urge a change to mandatory reporting to governmental authorities, which should also have a legal duty to investigate, issue appropriate public warnings, and share information across borders. This is not a role for the pharmaceutical industry, which has a serious conflict of interest.

While some drug companies have given public warnings to protect patients, others have been criticized for withholding information and, in a recent development in the United States, taken to court for failing to act. The industry is addressing the problem. In 2003, US pharmaceutical companies made an agreement with the US Food and Drug Administration (FDA) that they would report suspected counterfeit drugs to the FDA within five days of discovery (see "Companies That Have Warned"), although this remains a voluntary arrangement. In many poorer countries, where the problem is at its worst, there are no similar governmental and industry initiatives.

The Policy Forum allows health policy makers around the world to discuss challenges and opportunities for improving health care in their societies.

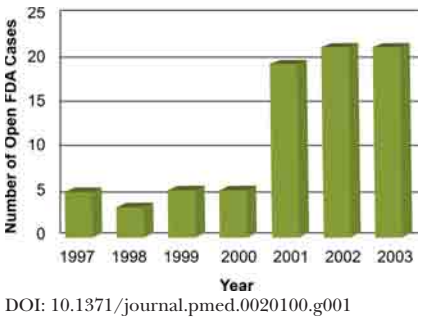
The Scale of the Problem

It has been estimated that up to 15% of all sold drugs are fake, and in parts of Africa and Asia this figure exceeds 50% ([1,2,3,4,5,6,7]; R. Jones, FDA spokesperson, E-mail statement, 18 November 2004). The FDA estimates that fake drugs comprise approximately 10% of the global medicine market (R. Jones, FDA spokesperson, E-mail statement, 18 November 2004). This estimate suggests annual criminal sales in excess of US$35,000,000,000 [1,2]. The number of investigations of possible counterfeit drugs by the FDA has jumped from about five per year in the 1990s to more than 20 per year since 2000 (Figure 1).

Most of the literature on fake drugs derives from local investigative journalism [6,8,9,10,11,12,13,14], with little scientific public health enquiry relative to the enormous scale of this criminal enterprise. The effects on patients of counterfeit medicines are difficult to detect and quantify, and are mostly hidden in public health statistics. The estimate of 192,000 patients killed by fake drugs in China in 2001 gives an indication of the scale of human suffering (see Sidebar).

Secrecy and Counterfeit Medicines

Most data on the epidemiology of counterfeit drugs are kept secret by



DOI: 10.1371/journal.pmed.0020100.g001

Figure 1. The Number of Investigations of Possible Counterfeit Drugs by the FDA Has Been Rising
(Figure: Margaret Shear, Public Library of Science, adapted from [39])

Citation: Cockburn R, Newton PN, Agyarko EK, Akunyili D, White NJ (2005) The global threat of counterfeit drugs: Why industry and governments must communicate the dangers. PLoS Med 2(4): e100.

Abbreviations: FDA, US Food and Drug Administration; GSK, GlaxoSmithKline; NAFDAC, Nigerian National Agency for Food and Drug Administration and Control; PSI, Pharmaceutical Security Institute; WHO, World Health Organization

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Competing Interests: NJW is on the editorial board of *PLoS Medicine*. RC, PNN, EKA, and DA declare that they have no competing interests.

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DOI: 10.1371/journal.pmed.0020100

the pharmaceutical industry and by governmental agencies. Drug companies employ investigators to track down and facilitate the shutting down of counterfeit industries, but this occurs very much in private.

There are no reliable accessible databases whereby health workers or the public can access current details of which products are being faked in a locality. It is obviously correct that information on anti-counterfeiting strategies and the sources of undercover intelligence should not be released, but we believe that the information on what drug is being counterfeited, and where, should be public knowledge [1].

Government Reluctance

Governments are also often reluctant to publicize problems with the quality of the drug supply in their country. This is reflected in the lack of action in much of the world regarding the problem of counterfeits, relative to their large impact on public health. The World Health Organization (WHO) has a reporting system and some of the information is publicly available [15]. The public information, crucially, does not include the country or region where the fakes were identified. However, the WHO has received no reports of counterfeit drugs from member countries after 2002, and it received only 84 reports between 1999 and 2002 [16,17].

In some countries, government officials have been accused of involvement in the false certification of counterfeit drugs, while in others, governmental agencies have been criticized for suppressing information [9,18]. The WHO in the Western Pacific region, an area severely affected by counterfeit drugs, is planning a rapid alert system for expediting the sharing of warnings and information between governments in the region.

Pharmaceutical Industry Survey

We wrote to the Pharmaceutical Security Institute (PSI) (see Box 1), which collates information on fake drugs obtained by the industry, asking whether they currently forwarded reports of counterfeit drugs to the relevant governments and the WHO. This question was not answered, but the PSI (in a letter dated 29 July 2003) informed us that, "Since its inception, it was recognized that a great deal of this information it [the PSI] contains would remain confidential and would not be disseminated. There is proprietary information that cannot be disclosed, either to peer member companies or to the general audience. Consequently, at this time the dissemination of information…is restricted and limited." The letter added that the PSI encourages its members to report counterfeiting incidents to the appropriate authorities, and that it fully supports the voluntary reporting to the FDA. We also wrote to 21 major companies, of the more than 70 pharmaceutical companies with offices in the United Kingdom, asking for information on the companies' policies on what action should be taken and who should be told when one of their products was found to be counterfeited. We have received replies from six companies; one (Merck Sharp and Dohme) declined to give any information, while three (GlaxoSmithKline [GSK], Bristol-Myers Squibb, and Novartis) stated that they would inform the local drug regulatory authority if they were notified that one of their products was being counterfeited.

Paucity of Warnings about Fake Drugs

That many pharmaceutical companies, professional organizations, and governments, both in developed and developing countries are not releasing warnings is manifested by the paucity of warnings relative to the scale of the problem. The industry's history of secrecy over data about fake drugs, and claims of a commercial motivation, go back over 20 years. In 1982, a spokesperson for the Association of the British Pharmaceutical Industry said, "It is difficult to declare a [fake drug] problem without damaging legitimate business" [13]. This impression of secrecy is supported by historical statements, such as the following: "The Society [Royal Pharmaceutical Society of Great Britain] is not issuing press releases [about counterfeit drugs] because it believes that as much as possible should be done behind the scenes…and that no great publicity should be sought because it could damage public confidence in medicines" [19]. But the Royal Pharmaceutical Society of Great Britain has recently revised its position. David Pruce, Director of Practice and Quality Improvement for the organization, told us (E-mail letter, 14 February 2005), "If

Recent Examples of Counterfeit Drugs

- Approximately one-third to one-half of packets of artesunate tablets, the pivotal, life-saving anti-malarial drug, recently bought in Southeast Asia were fakes, containing no active ingredient at all. A nongovernmental organization in a Southeast Asian country bought 100,000 inexpensive "artesunate" tablets only to find that they were counterfeit [7,39]. See Figure 2 for examples of fake artesunate being sold in mainland Southeast Asia.
- A total of 192,000 Chinese patients are reported to have died in 2001 from fake drugs, and in the same year Chinese authorities "closed 1,300 factories while investigating 480,000 cases of counterfeit drugs worth 57 million USD" [12]. In 2004, Chinese authorities arrested 22 manufacturers of grossly substandard infant milk powder and closed three factories after the death of over 50 infants [40].
- In North America, counterfeit atorvastatin [41], erythropoietin [41], growth hormone [33], filgrastim [33,41], gemcitabine [36,37], and paclitaxel [36,37] have been reported recently.
- Nigeria recently threatened to ban the import of all drugs from India, a major supplier, because of the high prevalence of counterfeits amongst the imports [42].
- In Haiti, Nigeria, Bangladesh, India, and Argentina, more than 500 patients, predominantly children, are known to have died from the use of the toxin diethylene glycol in the manufacture of fake paracetamol syrup [43,44,45].
- During the 1995 meningitis epidemic in Niger, the authorities received a donation of 88,000 Pasteur Merieux and SmithKline Beecham vaccines from neighbouring Nigeria. The drugs were found to be counterfeit, with no traces of active product. Some 60,000 people were inoculated with the fake vaccines [24].
- The recent discovery of counterfeit antiretrovirals (stavudine-lamivudine-nevirapine and lamivudine-zidovudine) in central Africa [46] raises the prospect of a disastrous setback in the treatment of AIDS in sub-Saharan Africa, unless vigorous action is taken now.

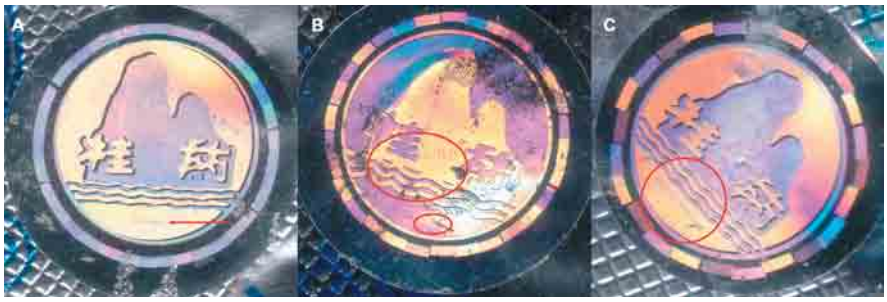
there is a risk that a patient has been dispensed a counterfeit medicine, then it is vital that they are informed. There have been two recent cases in Great Britain where counterfeit medicines appeared in the legitimate pharmacy supply chain. The public announcement of the problem of the counterfeit medicines was therefore entirely proper and necessary." He added, "It is important that news stories of this type are handled responsibly so that the public's confidence in their medicines is not undermined. This could deter patients from taking genuine medicines."

This assessment, that the dangers of causing alarm amongst the general public could outweigh the benefits of disclosure, remains widespread in public statements. A spokesperson for the Association of British Pharmaceutical Industries, Marjorie Syddall, wrote (E-mail letter, 20 October 2003), "A company should be completely satisfied that a medicine is counterfeit before informing the authorities, but more importantly still, before it makes this information known to the public—so that no unnecessary alarm is caused."

Commercial Motivation—"Cut-Throat Competition"

Chris Jenkins, a founding member of the PSI, now Associate Director of Pinkerton Consulting and Investigations, told us (E-mail statement, 9 December 2004), "It is necessary to keep fake drug information confidential for commercial reasons…to avoid media leaks and to prevent the possibility of rival drug companies taking unfair commercial advantage of a victim company." He explained, "At the outset, we [the PSI] were against having data online that anyone could interrogate…If a patient came to harm as a result of a counterfeit product, the company's good reputation is in danger of disappearing, together with a loss of confidence in the products… The one thing we were trying very hard to do was to keep it [data] out of the hands of the commercial people in any of the companies…The importance of meeting sales' targets is such that you can even find cut-throat competition between different operating divisions of the same company, let alone between two companies competing in the same market with similar drugs."

The WHO 1999 guidelines for the development of measures to combat counterfeit drugs states that "the reluctance of the pharmaceutical industry, wholesalers and retailers to report drug counterfeiting to the national drug regulatory authorities could impede the national authorities from successfully taking measures against counterfeiting", and suggests "the compulsory reporting to the relevant authorities of any incidents in which counterfeits are detected or involved" [20]. A recent review of the law and counterfeit drugs calls for the "eradication of the clandestine status of records and counterfeit drug information" [21]. At the International Conference of Drug Regulatory Authorities in Madrid in February 2004, it was stated by the WHO that "the drugs industry had a great deal of data but was 'very reluctant to make them available'" [17].



DOI: 10.1371/journal.pmed.0020100.g002

Figure 2. Genuine and Fake Guilin Pharma Artesunate Blister Pack Holograms Found in Mainland Southeast Asia
(A) is the genuine hologram attached to the blister packs of the genuine Guilin Pharma artesunate. The red arrow points to a legend stating "GUILIN PHARMA", which is visible with the naked eye as a thin strip below the waves, but can only be read with a microscope (letters are about 0.1 mm high).
(B) is a fake artesunate blister pack hologram: the upper red ring shows that the hologram has crescents, rather than a continuous blank line, between mountain and waves, and the lower ring shows that there is no "GUILIN PHARMA" legend.
(C) is also a fake artesunate blister pack hologram: the red ring shows that the "GUILIN PHARMA" legend is present but the letters are of larger font than those on the genuine hologram and can be read with the naked eye (letters are about 0.3 mm high).
A warning sheet giving more details and photographs is available in [47].
(Photos: Paul Newton, Wellcome Trust SE Asian Tropical Medicine Research Units)

Information Strictly Confidential

In the US it was reported that it had been "very difficult to obtain citable factual information about the extent of the problem of counterfeit drugs. Drug companies keep the information they have strictly confidential" [22]. In 1989, the British Department of Health and Glaxo (now a part of GlaxoSmithKline) were criticized for not publicizing information about the discovery in Britain of fake Glaxo Ventolin asthma inhalers. London's *The Times* obtained the fake Ventolin's licence and batch numbers for a story, prompting the release of the information. Warning letters, drafted by Glaxo and the Department of Health, were sent to all 14,000 pharmacists in Britain five weeks after the fake's discovery [8]. In 1998, the company Schering do Brasil was accused of keeping secret the discovery of oral contraceptive pills made of wheat flour for 30 days while they carried out their own investigation [23]. According to the *Far Eastern Economic Review*, the company was fined US$2.5 million by the Brazilian government [6]. Schering do Brasil informed us (E-mail letter, 17 February 2005) that "Federal Justice cancelled the fine in 2002 after the company appealed". In Niger, in 1995, one of the fake meningitis vaccines originating from Nigeria was labelled as made by SmithKline Beecham, but *Le Monde* reported that the company did not act against the counterfeiters, afraid that it might damage trade [24].

Fake Paediatric Anti-Malarial Drugs

The need to release fake drug information is acute in Africa, where a resurgence of malaria is killing an estimated one million people a year, the vast majority of them children under five [25]. One example

Box 1. The Pharmaceutical Security Institute

The PSI is a not-for-profit corporation formed by the major drug companies to collate their fake drug information to cooperate in fighting the racket. Based in Vienna, Virginia, United States, the PSI holds the only known comprehensive and updated source of fake drug information. The PSI Web site (www.psi-inc.org) states, "On a daily basis, many individuals unknowingly risk death or serious injury to their health by taking counterfeit pharmaceuticals." But its databank, which health workers see as holding key information to prevent patients from taking life-threatening fakes, is not accessible to the WHO, health authorities, or the public. Such is the secrecy of the PSI's information, that access is restricted even between its member companies, which include the 15 largest drug manufacturers.

highlights the problems encountered. One of us (K. Agyarko) found counterfeits of the GSK paediatric anti-malarial syrup halofantrine (Halfan) in August 2002 in Ghana. That month he prepared a public health warning. Agyarko and his deputy told the BBC [26] that he also alerted GSK's Ghana agent, who visited him with staff from GSK's London headquarters and took away samples of the fake Halfan. Agyarko publicly stated (on 23 September 2002, at the First Global Forum on Pharmaceutical Anticounterfeiting in Geneva, Switzerland) [26] that he was asked by GSK to withhold his public warning because it would "damage" their product. After his meeting with GSK, no warning was issued. In a written statement (E-mail letter, 24 October 2003), GSK denied receiving Agyarko's fake Halfan alert and said the company was "not provided with any samples of fakes by the authorities in Ghana".

After a year of enquiries, resulting in a BBC Radio programme (BBC Radio 4, "File on 4", 5 October 2004) [26], GSK reversed its position and said that its local agent had "bumped into" Agyarko and had received his alert and samples of fake Halfan syrup. In a new statement (E-mail letter, 5 October 2004) GSK said: "At no point was any pressure put on the Ghanaian authorities not to issue a public warning on fake Halfan." GSK's vice president of communications, Louise A. Dunn, told us (E-mail letter, 6 October 2004), "There was some confusion over the interactions with Mr Agyarko. The key point here is that there was no wrong doing…"

However, the Ghana incident needs to be viewed in the context of the wider illegal trade in fake Halfan syrup identified in West Africa, and GSK's reluctance to give us details about this trade. We asked GSK whether it had issued any public warnings about fake Halfan syrup, but the question was not answered. The only reference to counterfeit halofantrine syrup that we have been able to find in the public domain was published in a specialist technical journal that described the mass spectroscopy analysis of fake halofantrine syrups by the GSK Medicines Research Centre [27] and demonstrated that the fake syrups contained two potentially harmful sulphonamide drugs, but no halofantrine. We wrote to GSK (letter, 20 June 2003) asking when and where discoveries of fake Halfan were made, and whom GSK had informed about them. GSK told us only that "counterfeit Halfan is present in Nigeria and Sierra Leone" (letter, 21 July 2003). It gave no details of preparation type or discovery dates.

Fake GSK Halfan syrup was discovered in Nigeria in June 2002 by the Nigerian National Agency for Food and Drug Administration and Control. NAFDAC alerted GSK and issued a public health warning in June 2002 in the regular NAFDAC fake drug bulletin [28], giving the fake Halfan syrup's identifying details. The NAFDAC's Dora Akunyili told BBC Radio (5 October 2004): "It is more dangerous not to alert the public. We will still issue a warning even if we find it in only one shop. If you find any fake drug product in only one shop you can be sure it is in many villages…We don't defend companies. We are defending the people" [26].

The Pharmaceutical Board of Sierra Leone, which handles fake drug cases, was not informed by GSK of any discoveries of fake GSK Halfan syrup, according to its director Michael J. Lansana (E-mail letter, 21 January 2004), although it did receive a report of counterfeit adult Halfan caplets from GSK. Later, GSK told us (E-mail letter, 6 October 2004) the fake Halfan syrup it had tested was found in Sierra Leone in late 2001, and that it had informed Sierra Leone's Minister of Health and Sanitation of the find.

Only a single report of counterfeit halofantrine, which does not specify details of preparation type or location, is given in the WHO Counterfeit Drug Reports for 1999–October 2000 [15].

Cross-Border Threats and Cooperation

The fake Halfan syrup cases highlight the importance of communication and cross-border cooperation, and the need for industry and governments to inform neighbouring countries when a fake is found. The global distribution and the scale of the racket in fake adult Halfan capsules was clear in December 2000, when Belgian customs seized 57,600 packs of fake GSK Halfan capsules (and 4,400 packs of fake GSK Ampiclox [ampicillin] and 11,000 packs of fake GSK Amoxil [amoxicillin]) en route from China to Nigeria. The counterfeiters in China were found to be preparing to export 43 tons of 17 brands of drugs from seven international pharmaceutical companies [29].

Companies That Have Warned

Sometimes pharmaceutical companies have publicized information to alert health workers and patients and governments to the dangers of counterfeited or tampered products. For example, Johnson and Johnson, Serono, Hoechst, Wellcome Foundation (now part of GSK), GSK, and Genentech have publicized information on their drugs that have been counterfeited or tampered with. In 1982, cyanide-laced paracetamol killed seven people in the US. The pharmaceutical company whose product had been tampered with, Johnson and Johnson, issued alerts and cooperated with the investigation, and although the financial cost to the company was large, its long-term reputation was probably enhanced. Other companies, at least initially, did not take advantage of the disaster for their own financial gain [30]. In 2002, Johnson and Johnson issued 200,000 letters to health-care professionals in the US warning them of fake Procrit (erythropoetin) within one week of being notified of a severe counterfeit

problem [31]. In 1982, Hoechst voluntarily took out magazine adverts in Lebanon to warn pharmacists and customers of a fake of its drug Daonil (glibenclamide) for the treatment of diabetes mellitus [13]. In 2001, Serono was told by the FDA to issue a public warning to hospitals, clinics, and patients in seven US states after the discovery of a counterfeit of its drug Serostim, a human growth hormone used in the treatment of AIDS and other conditions [32]. In 1984, in Thailand, the Wellcome Foundation (now part of GSK) publicized the discovery of fakes of its antibiotic Septrin (co-trimoxazole) that lacked any active ingredients, and the company's efforts to stop its production. Wellcome also had reports that the fakes were being imported into the UK, which it made public along with the warning that it sent to the British Embassy in Bangkok [14]. In 2001, GSK made public the discovery of fakes of its AIDS treatment Combivir (zidovudine + lamivudine) [32], and Genentech publicized information on fakes of Neupogen (filgrastim) [33].

The Pharmaceutical Research and Manufacturers of America announced in April 2003 that, from 1 May 2003, its 60 members would voluntarily report to the FDA "within five working days of determining that there is a reasonable basis to believe their product has been counterfeited" [34]. This is an important local development but it should be mandated by law and become a global standard. Indeed, we have not found one country where drug companies have a legal duty to report discoveries of counterfeits of their products to public health or trade authorities.

The Sharing of Information on Counterfeit Medicines

We suggest that the pharmaceutical industry, which is such a benefit to our health, is harming both patients and itself by not vigorously warning the public of fake products when they arise. Apart from the moral imperative, there is the prospect of growing legal pressure on drug companies to take responsibility for fakes of their products. In Britain, there are proposals to introduce a charge of "corporate killing" for companies who have contributed to the deaths of customers [35] that could also apply to drug companies if they do not take reasonable steps to warn the public of a fake product.

Drug Companies Sued in the US

Already, the US has seen the first court case brought against two drug companies for allegedly failing to act to protect customers over a fake drug discovery. In 2002, a Kansas City pharmacist was jailed for diluting the anticancer drugs Gemzar (gemcitabine) and Taxol (paclitaxel). The victims and dead patients' families sued the drug companies, Eli Lilly and Myers Squibb, for not taking steps to stop him. The companies argued that they had no duty to protect the plaintiffs from the pharmacist's criminal acts, but a newspaper reported that Eli Lilly and Myers Squibb settled out of court, apparently for US$72 million, avoiding a legal precedent that would hold drug companies liable for not disseminating such information [36,37].

Chris Jenkins suggests that the PSI could face a legal challenge to open its fake drug databases (E-mail, 9 December 2004): "Only the PSI had an overview of the known racket…In theory, every fake drug case reported by the companies should be on there." He is concerned that private investigators could be liable for fake drug data they obtain for client companies.

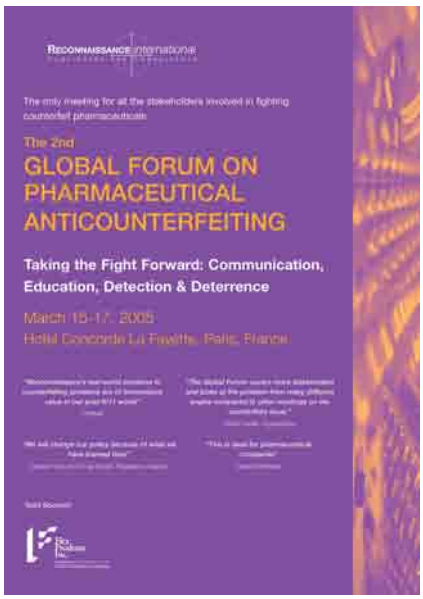
Governments Must Enforce a Legal Responsibility

We believe that the industry, along with pharmacists, health workers, and governments, needs to extend the "behind the scenes" fight against fakes to a public collaborative approach with a legal responsibility to report suspected counterfeits to drug regulatory authorities, in a similar way to the reporting of "notifiable" infectious diseases. The drug regulatory authorities, accountable to the consumers of drugs, should have a statutory duty to investigate and disseminate the information, with the interests of patients as the prime concern. Drug regulatory authorities in economically poor countries will need additional financial support.

We recognize that false information could seriously damage a company and that information should be verified and used prudently. We also recognize that careful public information measures will be needed to prevent patients from stopping the use of genuine products, but suggest that this is possible as pharmaceutical companies can, and have, alerted the public in collaboration with government agencies (see above). However, the decision to warn the public should not be made by the pharmaceutical industry alone, which has a serious conflict of interest. We believe that the long-term interests of both the industry and patients are best served by more openness and social responsibility to public health. Company staff and shareholders should not be in a position to adjudicate conflicts

DOI: 10.1371/journal.pmed.0020100.g003

A collection of counterfeit pharmaceutical drugs seized by the NAFDAC in Nigeria
(Photograph: NAFDAC/International Chamber of Commerce Counterfeiting Intelligence Bureau)



DOI: 10.1371/journal.pmed.0020100.g004

Figure 3. Poster Advertising the Second Global Forum on Pharmaceutical Counterfeiting (Figure: Ian Lancaster, Reconnaissance International)

between commercial gain and public health—such adjudication should be in the hands of government departments accountable to the public.

Aviation Industry Model

The UK Civil Aviation Authority provides a model: suspected unapproved aircraft parts must, by law, be reported to it [38]. When a report of a counterfeit drug is confirmed, the drug regulatory authorities should be responsible for assessing the public health importance of the information and deciding when and how to alert the country's police, trade, customs authorities, and public, and also the drug regulatory authorities of other countries that may be affected, with the assistance of Interpol as required. If a drug regulatory authority is confident, for example, that the fake drug has been intercepted before it has reached the pharmacies, a public alert may not be necessary. The "confusion" reported in the GSK Halfan syrup case also illustrates the great importance for both companies and government departments to keep a secure paper trail of information so that it is clear what has happened and when.

The pharmaceutical company is also a victim of the counterfeiter and should be supported by governmental authorities if it reports promptly. Individuals who report information on counterfeit drugs should remain anonymous and be protected from the criminal counterfeiting underworld, which may exact retribution. International agreements between companies to avoid taking advantage of competitors' misfortunes, when precipitated by rumors or confirmed reports of fake drugs, may facilitate enhanced cooperation within the pharmaceutical industry.

International Convention against Counterfeit Drugs

The Madrid meeting in 2004 considered a proposed international framework convention on counterfeit drugs, presented by the WHO, to promote international cooperation and the exchange of information [17]. If enacted this could be a very important contribution to improving drug quality. The effective control of the global epidemic of counterfeit and substandard drugs will not be easy, and will need a multifaceted approach: the provision of effective, available, and inexpensive drugs; the enforcement of drug regulation; more openness by governments as to the scale of the problem; more effective police action against the counterfeiters and those who may be corrupt allies within government and industry; enhanced cooperation between the industry, police, customs, and drug regulators; and enhanced education of patients, drug sellers, and health workers [4,5,20]. We urge the industry and governments to act, through the sharing of crucial public health information, to facilitate the protection of patients and improve the quality of an apparently deteriorating drug supply.

Counterfeit Drug Conference in Paris

On 15–17 March 2005, the Second Global Forum on Pharmaceutical Anticounterfeiting will convene in Paris, where representatives of the major pharmaceutical companies, governments, medical and scientific professionals, law enforcement agencies, nongovermental organizations, and private investigators will meet to discuss the growing problem that threatens patients and the pharmaceutical industry (Figure 3). ■

Acknowledgments

We are very grateful to Dr. Lembit Rago, WHO Essential Drugs and Medicines Department; Dr. Allan Schapira, WHO Roll Back Malaria Department; John Anderson, Chairman of the Global Anti-Counterfeiting Group; Mark Morris, *Kansas City Star*; Erik Madsen, Interpol; Danièle Letoré, Genevensis; and Marie Ose, Agence France Presse. We are very grateful to Professor Marcus Reidenberg, Cornell University, and Michael Lansana, Head of the Pharmaceutical Board of Sierra Leone, for their support for the arguments put forward in this article. PN and NJW are supported by the Wellcome Trust of the UK.

Author contributions. All authors researched the information for this review, RC and PNN wrote the first draft, and all authors contributed to writing the final version of the manuscript.

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Drugs

FDA Initiative to Combat Counterfeit Drugs

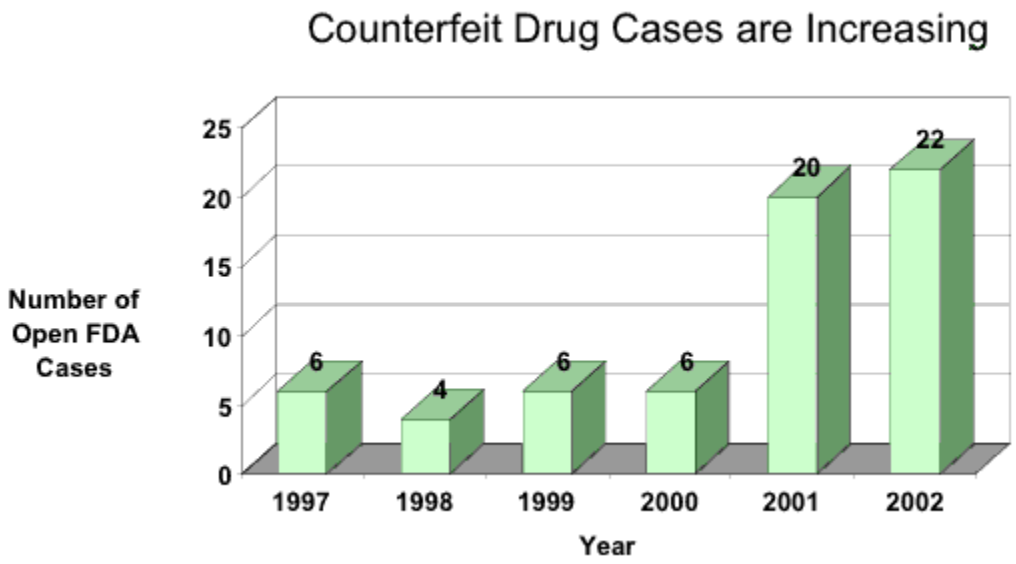
In an effort to protect against the rising occurrence of potentially unsafe counterfeit drugs reaching consumers, FDA is announcing a new initiative to more aggressively protect American consumers from the risks posed by counterfeit drugs. As part of this effort, FDA has created a new internal task force that will develop recommendations for steps FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs getting into the supply chain.

Background on Counterfeit Drugs

Risks of Counterfeit Drugs

Counterfeit drugs pose potentially serious public health and safety concerns. They may contain only inactive ingredients, incorrect ingredients, improper dosages, or even dangerous sub-potent or super-potent ingredients. Drug counterfeiting is a relatively rare event in this country; however, FDA has seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about 5 per year through the late 1990s.

In addition, counterfeiting in recent years has shifted increasingly into “finished” pharmaceuticals (the final product taken by the patient) as opposed to counterfeiting of “bulk” drug ingredients in the past. As drug manufacturing and the distribution system have become more complex, there are increased opportunities to introduce more legitimate appearing products into the drug supply in the U.S., and the challenge of protecting against unsafe counterfeit drugs has become more difficult.



Even a small percentage of counterfeit drugs in the drug supply can pose significant health risks to thousands of Americans. In recent years, FDA has encountered a range of counterfeit drugs that illustrate the public health threats posed by counterfeiters drugs:

Toxic Effects: Some fake drugs contain ingredients that, if ingested or injected, can cause health problems. For example, the recently counterfeited Procrit, an important drug for cancer and AIDS patients, contained nonsterile tap water, which can cause an infection in the bloodstream.

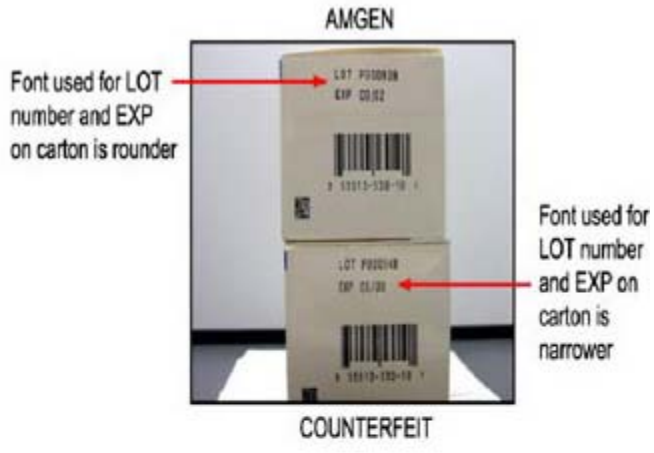
Unintended Effects: Some counterfeits substitute one drug for another. For example, insulin has been substituted for a more expensive injectable drug. And last year, counterfeiters emptied bottles of Zyprexa, a drug used for schizophrenia and acute bipolar mania, and replaced them with white tablets imprinted with the word “aspirin.”

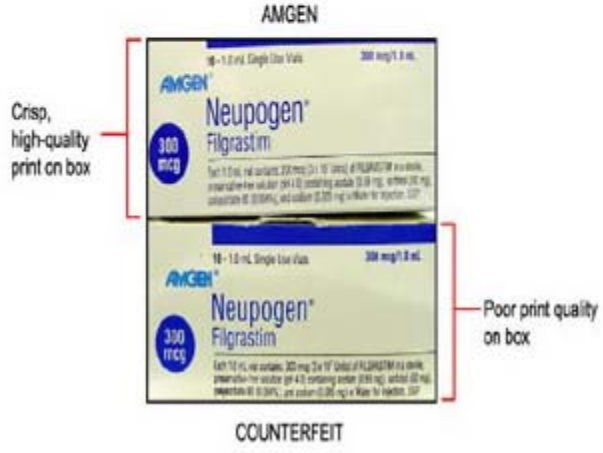
Ineffective Treatments: Some fake drugs contain some active ingredient, but are subpotent. Others attempt to accurately copy the real drug, but still pose safety risks because they are not formulated in a way that achieves the right therapeutic levels in the patient’s blood.

No active ingredients: Some counterfeit drugs have no active ingredients. For example, a counterfeit version of Serostim, a growth hormone used in AIDS patients, was found to have no active ingredient.

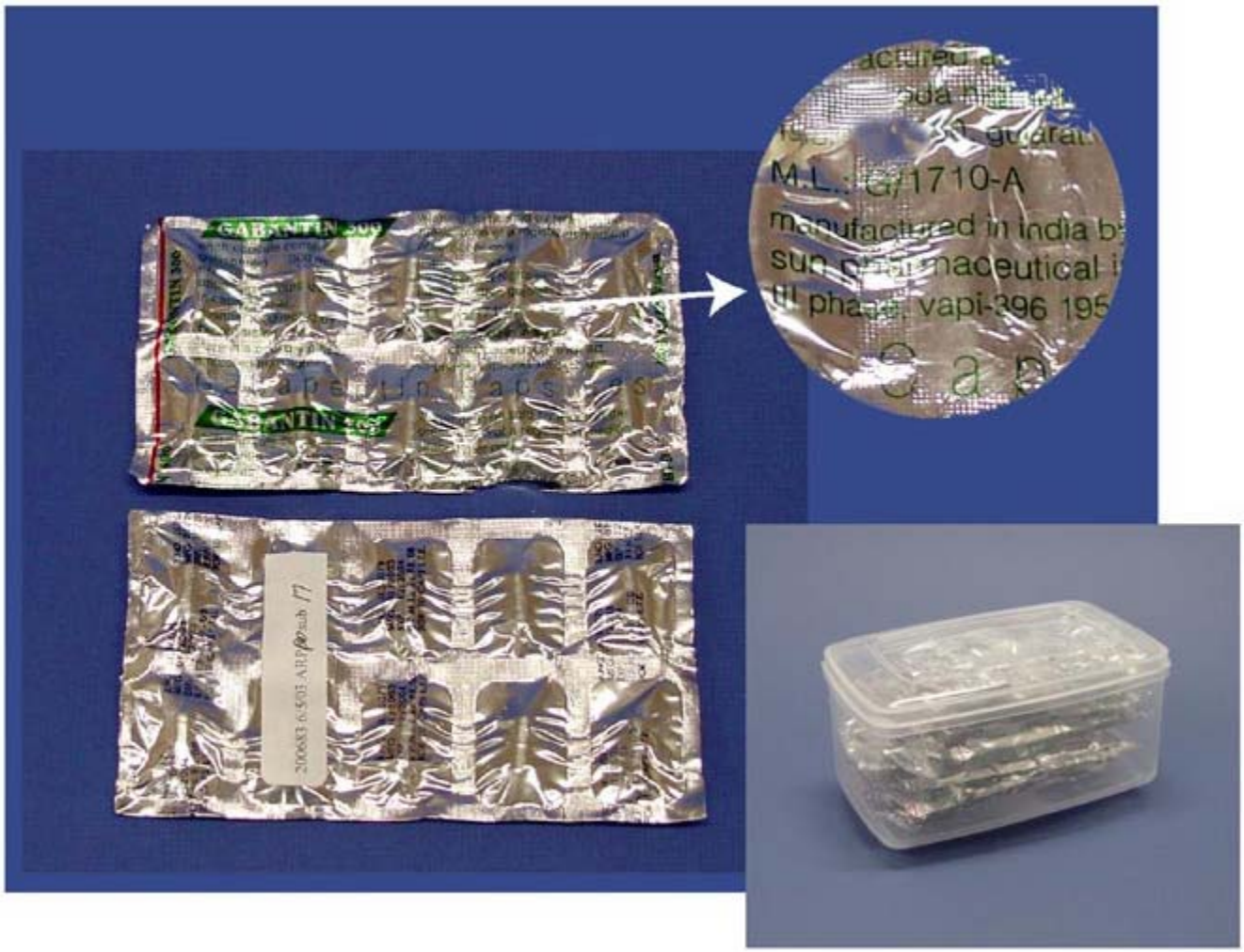
Labels that look real: Over the past several years, counterfeiters have gained access to sophisticated technologies that enable them to very closely duplicate the packaging and labeling of legitimate prescription drugs. In fact, labeling for a product can be so exactly duplicated that it may require extremely close inspection by experts in order to identify subtle differences from the legitimate product.

Counterfeit duplication of product labeling example





Drugs purchased over the Internet by an American patient who was told that the products were manufactured in the United States and were being sold from Canada. The drugs he actually received are fake “knockoffs” from India.



In all of these cases, at a minimum, patients face the risk of therapeutic failures or worsening of the health problem that the drug was intended to treat. Sometimes, toxicities can be potentially much worse. While no fatalities have been causally linked to specific counterfeit drugs in the last decade, criminals who engage in such counterfeiting practices clearly have disregard for the well-being of ill patients and the safe practices of legitimate companies and individuals involved in the distribution of prescription drugs.

The movement of legitimate pharmaceuticals in this country relies on the wholesale industry. Primary wholesalers purchase drugs directly from manufacturers and then sell the products directly to a pharmacy, hospital, institution, other dispenser, or secondary wholesaler. In the U.S., three primary wholesalers account for 90% of the prescription drugs distributed in this country. Occasionally, when low-cost drugs are available (e.g., because of temporary excess in the supply of a drug), primary wholesalers purchase from secondary wholesalers. Secondary wholesalers usually deal in smaller quantities and have

higher turnover of stock. But in some instances, some smaller wholesalers also knowingly or unknowingly take higher risks by obtaining drugs that may not have a clear “pedigree” traceable back to a legitimate manufacturer. Unlicensed or unregulated pharmacies may also knowingly or unknowingly distribute unapproved drugs. Counterfeit drugs entering the U.S. distribution supply chain can find their way into the system through the secondary wholesale market, where drugs can change hands several times before reaching the end user. Such drugs can also enter the U.S. market via disguised imports from other countries, or through the purchase by American consumers of drugs through the internet.

Because counterfeiting is difficult to detect, investigate, and quantify, it is hard to know the true extent of the problem. Outside the United States, drug counterfeiting is known to be widespread and affect both developing and developed countries. For example, in South-East Asian countries approximately 10% of drugs on the market are believed to be counterfeit. In China, authorities believe that for some drugs, the estimated average counterfeit copies can be as high as 50%. It is reported that in underdeveloped countries such as Argentina, Colombia, and Mexico, up to 40% of manufactured pharmaceuticals are believed to be counterfeit.

In 1988, the Prescription Drug Marketing Act (PDMA) was enacted as an effort to ensure that prescription drug products in the U.S. would be safe and effective and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs were being sold to the American public. The PDMA sought to introduce safeguards into the drug distribution system to provide assurances through paper records of the true source and distribution history (“pedigree”) of a prescription drug. While the PDMA provided some protections, it has important limitations:

- Some of its provisions have made it possible for determined counterfeiters to skirt its intent.
- Its reliance on paper records can be quite costly, especially for small- and medium-sized wholesalers. Also, paper records can be easily forged.
- PDMA does not envision the use of modern technologies that can assist with tracking or verifying the authenticity of legitimate prescription drugs.

In the 15 years since PDMA was enacted, there have been many changes in the industry and in anti-counterfeiting technologies, as well the introduction of electronic ordering, inventory control, and record-keeping used by the pharmacies—which may provide more effective mechanisms to achieve PDMA’s goals.

FDA’s Current Efforts to Protect Americans from Counterfeit Drugs

FDA is committed to an aggressive enforcement strategy to combat counterfeit drugs. FDA has initiated 73 counterfeit drug investigations from October 1996

through June 2003, the majority having begun in the last 2 ½ years. These investigations have so far netted 44 arrests and 27 convictions, with a number of criminal investigations ongoing. Fines and/or restitution have been imposed in excess of $250,000. FDA works closely with federal, state, and local agencies, as well as the private sector, to identify and track down drug counterfeiters. Much of the activity has targeted high volume, high cost drugs where counterfeiters attempt to make the most money possible in a short time period. Drugs at risk for counterfeiting are often those found in the top 20 best selling prescription medications, including widely used cholesterol-lowering drugs, high blood pressure drugs, AIDS drugs, drugs used to raise red blood counts, and drugs used to fight depression.

FDA has public and private partners in this effort. FDA has been working closely with the U.S. Bureau of Customs and Border Patrol to identify suspect packages that may contain counterfeit drugs that cross into the U.S. from other countries and enter into the U.S. distribution system. This is a challenging task because there are a very large number of small packages entering the U.S. every day, many containing drugs purchased via the internet. Also, these small drug shipments, when consolidated by the addressee, can find their way into the secondary wholesale market. FDA has alerted consumers in the past of the significant risks associated with drugs purchased over the internet from unknown sources.

Under a voluntary program just begun, drug manufacturers will notify FDA within five working days of determining that there is a reasonable basis to believe that a product has been counterfeited. The program extends to counterfeits discovered in foreign countries if there is clear evidence to believe that they are intended for distribution in the U.S. The program went into effect in May, and it has already been used to provide several reports of counterfeit drugs to FDA, including those involving Procrit, and Lipitor, a widely prescribed cholesterol-lowering drug.

While FDA is seeking to improve deterrence and detection of counterfeit drugs, enforcing the law against health care criminals is a core part of FDA's efforts to protect Americans from counterfeit drugs. Many of these counterfeit enforcement activities are the work of the FDA's law enforcement arm, the Office of Criminal Investigations (OCI) in conjunction with other state and federal enforcement officers. For example, for the Procrit counterfeiting case, FDA's OCI worked closely with Florida law enforcement officials in the investigation, arrest, and conviction of the counterfeiters.

Details of FDA's New Initiative To Combat Counterfeit Drugs

To respond to the increased sophistication and increased opportunities of drug counterfeiting **before** it becomes a widespread problem, FDA's new Counterfeit Drug Initiative is designed to better identify the risks and threats from

counterfeit drugs, to coordinate public and private efforts to fight counterfeiters, and to identify technologies and tools to aid in identifying, deterring, and combating counterfeiting. A new internal FDA Counterfeit Drug Task Force will be charged with exploring measures to be taken to prevent patients being exposed to counterfeit drugs.

Some of the areas that the FDA Task Force will explore include:

- **Technology.** The task force will examine currently available and potential, future, low-cost technologies that can be used to assure product and package integrity and track legitimate products through the distribution chain. Known technologies include those visible to the naked eye, such as inks and watermarks. These features could be used with existing packaging and the existence of such a mark would help consumers and pharmacists identify counterfeit drugs. In some cases covert features may be used to authenticate products when used with special equipment (e.g., magnifying lens, special lamps). However, one limitation of packaging technologies is that, if they are not linked inextricably to particular drug product (e.g., using marks on “blister packs” or similar technology), it is possible that counterfeiters would repackage illegitimate drugs in legitimate packaging. Moreover, it may be costly and time-intensive to use the tools required to authenticate such printed package labels. In addition, incorporation of one or more substances into the drug product itself, (e.g., taggants) may also be useful in distinguishing legitimate from counterfeit drugs. Technologies are being developed to track products through the distribution chain. These include bar coding and radio frequency chips. These technologies are able to transmit a great deal of very specific information about the product and can enable distributors and retailers to track products through the entire distribution network. Although many of these technologies are not now mature and have limitations, and further cost-benefit analysis is needed, they offer great promise as counter-measures to make legitimate prescription drugs more secure from counterfeiters.
- **Border Study.** With assistance from U.S. Customs and Border Protection, the task force will initiate a study of pharmaceuticals entering the United States at several major ports of entry, to better determine the type and extent of drugs arriving from overseas and the degree to which counterfeit drugs are among such imports.
- **Alert System.** The task force will seek to improve upon the current counterfeit alert system to enhance communication about known or suspected counterfeit products to all parties in the distribution supply chain.
- **Strengthen Distribution System.** The group will identify mechanisms to strengthen the wholesale distribution system, such as helping create a model code of conduct for wholesalers and strengthen the model practice

act for wholesale distributors for States to adopt. The goal is to increase protection of consumers without burdensome costs.

- **Engage Private Sector Stakeholders.** The task force will gather private sector information and collaborate with pharmacy and health professionals, drugs manufacturers and distributors, consumer organizations, and other stakeholders on how to best counter these criminal practices.
- **Engage Other Government Agencies.** The task force will improve coordination with other government agencies, including the U.S. Customs and Border Protection Service, the Treasury Department, the Department of Justice, and States, who have experience with counterfeiting.
- **Public Education.** The group will recommend ways to educate consumers about steps they can take to minimize risks associated with counterfeit drugs. It will also educate consumers about what to look for, and what to do, if they suspect they have received a counterfeit drug.
- **Higher Penalties.** The task force will explore the potential deterrence and other effects of stiffer penalties on those found guilty of counterfeiting prescription drugs in the U.S. are needed (For example, the current penalty for counterfeiting a drug label is 10 years in prison, but for counterfeiting the actual drug may only be 3 years.)

Task Force Reports

In about two months, the FDA task force will issue an interim report with recommendations for public comment. Following input from interested parties on the report and recommendations, FDA intends to finalize the report within six months and to issue a strategic action plan outlining pubic and private sector actions needed to address the growing concern about counterfeit drugs.

U.S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Microgram Bulletin

Published by:
The Drug Enforcement Administration
Office of Forensic Sciences
Washington, DC 20537

The U.S. Attorney General has determined that the publication of this periodical is necessary in the transaction of the public business required by the Department of Justice. Information, instructions, and disclaimers are published in the January issues.

VOL. XXXVII, NO. 4 APRIL 2004

- INTELLIGENCE ALERT -

STONERS AND BUDDAFINGAS CANDY BARS (CONTAINING THC) IN SAN FRANCISCO, CALIFORNIA

The Division of Forensic Toxicology, Armed Forces Institute of Pathology (Rockville, Maryland), recently received two apparent candy bars labelled as Stoners and Buddafinga, that were visually similar to the commercial candy bars Snickers® and Butterfingers® (see Photo 1, right, and 2, next page). The bars, which weighed approximately 60 g each and were packaged in foil wrappers, were forwarded to the laboratory by the Coast Guard Marine Safety Office, San Francisco Bay, where they had been provided by a defense attorney for a merchant marine who tested positive for the tetrahydrocannabinol (THC) metabolite, THC-COOH, during a random urinalysis.

Photo 1

Following a multi-step liquid/solid extraction workup, analysis by GC-MS analysis confirmed THC at 360 micrograms/gram and 496 micrograms/gram for the Stoners and Buddafinga bars, respectively (equalling 21.6 and 29.8 milligrams of THC in the submitted bars). This was the first submission of these products to the laboratory.

Photo 2

[Editor's Notes: A similar exhibit of a "Stoners" candy bar was reported in the February 2004 issue of *Microgram Bulletin*. This is the first report of the "Buddafingas" candy bar. The "Buddafingas" wrapper lists the product as "TaiNTed / Buddafinga / diggety, dankity, peanut-buttery!" and a consumer warning "For MEDICINAL Use Only". Both product wrappers also include marijuana leaf logos - it is therefore difficult to understand why anyone would attempt to present them as an explanation for "unknowingly" ingesting THC.

The source for these bars is currently unknown. An Internet search lists "Tainted Truffle" (a sub-title on the "Stoners" candy bar) as a supporting organization for a California based marijuana legalization lobbying group, with no further information. There is nothing on "Stoners" or "Buddafingas". A number of *Microgram* subscribers have requested information on the source of these products; therefore, if any subscriber is aware of that source, please forward that information to the Editor at: microgram_editor@mailsnare.net]

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- INTELLIGENCE ALERT -

COUNTERFEIT METHYLPHENIDATE (RITALIN) TABLETS CONTAINING OXYCODONE IN SANTA ROSA, CALIFORNIA

The California Bureau of Forensic Services Laboratory (Santa Rosa, California) recently received an apparently routine submission of four white tablets, diameter approximately 7 millimeters, with an "M" in a box on one side and scored with a "5" on the other, presumed methylphenidate (see Photos 3 and 4). The tablets were seized by the Santa Rosa Police Department pursuant to a routine traffic stop. The presumptive identification was based on the Drug Identification Bible (2003 edition, pps. 162 and 266), indicating a Mallinckrodt Inc. product (Methylin®) containing 5 milligrams of methylphenidate. Analysis by GC/FID and GC/MS, however, indicated not methylphenidate but rather oxycodone with a trace of dihydrocodeinone (not quantitated). This was the first such submission to the laboratory.

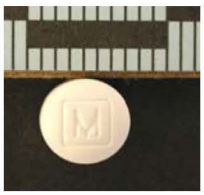

Photo 3

Photo 4