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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee Report
And Report of the Work Group on E-Pedigree

Stan Goldenberg, RPh, Chair and Board Member
Bill Powers, Board President
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There has been no Enforcement Committee meeting since the Enforcement Committee Meeting held in conjunction with the January 23 Board Meeting. Minutes of the January 23 meeting are provided as **Attachment A** at the back of the packet.

On March 25, 2008, the Board of Pharmacy delayed implementation of the e-pedigree requirements from January 1, 2009 until January 1, 2011. This decision was made at a board meeting held that day.

I: Work Group on E-Pedigree:

A. Presentations on E-pedigree Implementation

Several presentations are planned for this meeting. Announcements about the specific speakers will be made at the board meeting, as confirmation of several speakers is currently pending.

In **Attachment 1** are some of the materials found on the Web sites of various drug manufacturers developed to educate the public about counterfeit medicine. These are excellent resource documents for the public on the dangers of counterfeit medicine.

I have also enclosed several general articles on counterfeiting.

B. Discussion and Action Regarding Implementation of Electronic Pedigree Requirements for Prescription Medicine in California

During this segment of the meeting, the board will have the opportunity to discuss e-pedigree implementation.

C. and D.
Discussion and Action Regarding Submission of Comments to the FDA on the Standardized Numeric Identifier and Technologies for Drug Identification

The FDA has requested comments from interested parties on the two areas listed above – on identification of a standardized numeric identifier and on technologies necessary for track and trace. Comments are due May 19, 2008.

The board may wish to provide comments to the FDA in this area.

In **Attachment 2,** Deputy Attorney General Joshua Room provides an overview of both federal requests for comments. Copies of the Federal Register are also included.

Mr. Room's statement provides a framework for board discussion.

The board may instead encourage adoption of standards by a specific date, provide comments in support of the process, or provide no comments at all.

II. Other Enforcement Matters

E. Discussion Regarding the Senate Committee on Business, Professions and Economic Development's Review of the Medical Board's Impaired Physicians Program and the Other Departmental Substance Abuse Programs for Licensees, including the Pharmacists Recovery Program

On March 12, the Senate Business, Professions and Economic Development Committee held a public hearing on the department's substance abuse programs for licensees run by various healing arts boards. This review was initiated following the Medical Board's decision to repeal its statutory provisions for their Impaired Physicians Program.

The committee is interested in identifying how other healing arts boards operate their programs, with a look to standardizing some characteristics about these programs to protect the public. No additional details are available at this time, but I suspect there may be a legislative proposal developed this year on this subject

In **Attachment 3** there is a copy of the board's responses to a number of questions requested by this Senate committee. Also included are background documents used by the committee.

F. Discussion: Medication Errors

On April 11, the Joint Commission issued a report about an alarmingly high number of medication errors in the inpatient setting. To quote from the press release:

> Medication safety is a big problem for small children. Young patients are at greater risk for drug errors because most medications are formulated and packaged for adults and most health care settings are built around the needs of adults. A study in the April issue of *Pediatrics* says that medication mix-ups, accidental overdoses, and bad drug reactions harm roughly one out of 15 hospitalized children. This *Alert* covers the steps that are critical to reducing pediatric medication errors.

A copy of the "Sentinel Event Alert" is provided in **Attachment 4**. Also included in this tab are some recent articles on medication errors.

During this meeting, the board may wish to discuss what action it desires to initiate in the future in light of this report.

Additionally, at the July 23, 2008 Board Meeting, Michael Cohen from the Institute for Safe Medical Practices, will discuss medication errors in general in a presentation to the board.

G. Presentation by Supervising Inspector Robert Ratcliff, PharmD

If time permits, Supervising Inspector Ratcliff will provide a presentation titled: "Surviving a Board of Pharmacy Inspection." This is part of a continuing education course the board provides at pharmacist association meetings. The presentation has been scheduled for this board meeting to provide an overview to board members of what occurs during a routine inspection.

If there is insufficient time to hold this presentation at this meeting, the presentation will be scheduled for a future meeting.

H. Enforcement Statistics

Attachment 5 contains enforcement statistics for the first three quarters of this fiscal year.

I. Third Quarterly Report on Enforcement Committee Goals for 2007/08

At the back of this tab section is the strategic plan update for the Enforcement Committee.

Attachment 1

Information on Counterfeit Drugs

Rx

Counterfeit and Importation

Counterfeit Q&A

Importation

Helpful Web Sites

Additional Resources

Health Care Professionals

Animal Health

Counterfeiting medicines is on the rise in the United States and around the globe putting patients at risk.

This product information is intended only for residents of the United States.

Counterfeit medicines are dangerous by their very nature – they are not produced under safe manufacturing conditions and they are not inspected by the regulatory authorities. Therefore, it is impossible for consumers to know what ingredients these products actually contain.

In recent years we have seen a spike in counterfeit medicines in the legitimate medicine supply chain. While the United States is fortunate to have a pharmaceutical distribution system that is generally considered to be among the safest in the world, new cases of counterfeit medicines are emerging every day and Pfizer is not exempt from being targeted.

"Counterfeit medicines put patients' lives at risk. They undermine the core principles and morals of our business. As the world's largest pharmaceutical company, Pfizer is taking the lead to secure delivery of our medicines and to protect patients around the world." – John Theriault, Vice President, Pfizer Global Security

Even in countries generally considered "safe," such as Canada, the United States, and many of the European Union, counterfeit medicines have entered the legitimate supply chain, including counterfeit Lipitor®, Norvasc®, Viagra®, and Celebrex®. During 2006, more than 8.1 million counterfeit Pfizer medicines were seized.

A number of factors have contributed to this rise in criminal counterfeiting activity. Included among them are the growing involvement in the medicine supply chain of under-regulated wholesalers and repackagers, the proliferation of internet pharmacies, advancements in technology that make it easier for criminals to make counterfeit medicines, the increased importation of medicines from Canada and other countries, and the relatively small risk and penalty faced by counterfeiters.

Pfizer believes that there is no higher priority than ensuring that consumers have safe and effective medicines. To realize this goal, both industry and regulators must work

pharmaceutical supply chain.

For its part, Pfizer is identifying new technologies it can employ to make its packaging more counterfeit-proof. For example, Pfizer was the first pharmaceutical company to add Radio Frequency Identification (RFID) technology as part of a comprehensive safe-packaging program, including installing RFID tags on all Viagra® marketed in the United States.

"The research shows that [the problem of] counterfeiting of medicines is on the increase, and it's a substantial one. Globally we estimate the business is worth in excess of $35 billion a year and we predict that at a growth rate of between 12-16%, it will reach a value of $75 billion by 2010." – Peter Pitts, Director of the Center for Medicine in the Public Interest

Recognizing that there is no "catch-all" solution, Pfizer is working closely with the U.S. Food and Drug Administration (FDA) and other regulatory authorities to ensure that pharmaceutical companies have the resources they need to implement the anti-counterfeiting technologies that work most effectively for their products. Pfizer is working collaboratively with wholesalers, pharmacies, customs offices worldwide, and law enforcement agencies to increase inspection coverage, monitor distribution channels, and improve surveillance of distributors and repackagers.

Pfizer has also created a diversified international team to rapidly address product integrity issues as they arise and work proactively to stop them from occurring. The team has focused on putting into place business practices designed to protect patient health, increase cooperation with law enforcement agencies to prosecute counterfeiters, and promote public policy that will help eliminate counterfeiting.

Addressing this rising threat requires a sophisticated, coordinated, and united response. Pfizer recognizes that in addition to its own initiatives, partnerships must be forged across government agencies, the health care community, patients, and third-party stakeholders, to ensure that patients have a safe supply of medicines and that justice is served to those who put patients' lives at risk.

We ask you to join us as a partner in this fight to protect patient safety.

To learn more, visit these sections:

Read common counterfeit question and answers

Visit helpful Web sites

Access additional resources

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Rx

Counterfeit and Importation
- Counterfeit Q&A
- Importation
- Helpful Web Sites
- Additional Resources

Health Care Professionals

Animal Health

Counterfeit Q&A

This product information is intended only for residents of the United States.

How do you know when you've purchased a counterfeit product?

What are the dangers of taking counterfeit products?

How can you avoid buying or receiving counterfeit products?

How serious a problem is the counterfeiting of prescription medicines?

What are the causes of counterfeiting?

What are the consequences of counterfeiting?

What is Pfizer doing to combat the counterfeiting problem?

What can be done to improve the situation?

What can you do to help?

How do you know when you've purchased a counterfeit product?

Consumers may not know that the medicines they've purchased are counterfeits. That's why it's important to purchase prescription products from a pharmacy and pharmacist with whom you're familiar.

In some cases, patients have noticed a different taste, consistency, or appearance of products that are later identified as being counterfeit, or they may have a different reaction to the counterfeit drug.

If you suspect the Pfizer product you have pruchase may be counterfeit, contact us at 1-800-438-1985.

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What are the dangers of taking counterfeit products?

One of the biggest concerns is that you may not be getting the therapeutic benefit you expect from the product. For example, a drug you count on to lower your cholesterol level—or to shrink a cancerous tumor—may not be providing any benefit at all because

could be harmful. A fake drug also could interact with other medications you're taking and create potential health issues.

Counterfeit products may be manufactured in substandard environments without appropriate controls that ensure their safety and efficacy and they could contain dangerous contaminants.

Given the present environment in which we live, there also is a concern that counterfeit drugs could be used as a tool by terrorists.

Finally, counterfeit products undermine the basic tenet of our health care system: to enable people to live healthier, happier lives.

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How can you avoid buying counterfeit products?

The best way to avoid counterfeit drugs is to purchase prescription medicines at your local pharmacy from a reputable pharmacist whom you know.

Before you fill your prescription online, always see your doctor and get a written prescription first. You should also use an online pharmacy certified by the National Association of Boards of Pharmacy (NABP) when you buy prescription medicines online. This association helps ensure the quality and safety of every online prescription. The NABP's Verified Internet Pharmacy Practice Sites (VIPPS™) program only certifies pharmacies that meet state licensing and inspection requirements. Use the VIPPS certified pharmacy list to choose a VIPPS™–approved online pharmacy when buying prescription medicines online.

Don't buy medications from online pharmacies that aren't licensed in your country or that offer to write prescriptions or sell medications without prescriptions.

Where available, ask for the product in the manufacturer's original package.

Avoid drugs in foreign packaging because unregulated imports have been a way for counterfeits to enter the U.S. market.

Closely scrutinize the appearance of your medicine and its packaging. Talk to your pharmacist if you notice anything unusual, or if you have a different reaction to your medicine.

Report suspected counterfeiting to the FDA MedWatch Program (or 800-FDA-1088) and to the manufacturer. If you suspect the Pfizer product you have purchased may be counterfeit, contact us at 1-800-438-1985. Remember that if the price of a medicine seems too good to be true, it probably is.

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How serious a problem is the counterfeiting of prescription medicines?

The United States has a distribution system that is generally considered to be among the safest in the world.

While the vast majority of the prescription drugs that U.S. consumers buy are safe and effective, counterfeiting is increasingly becoming a more serious problem. The U.S.

increased dramatically over the past several years. In 2000 the FDA opened six counterfeit drug cases and in 2004 they opened 58 cases - a nearly ten-fold increase. And it is not just the U.S. that is seeing an increase. In the United Kingdom in 2004, seventeen incidents were reported and in 2005, forty-six; a 270% increase in counterfeiting incidents in one year.

In June 2005, following the discovery that an accredited pharmacy in Canada had dispensed counterfeit Norvasc®, Pfizer's popular blood pressure medicine – 11 reported deaths were examined for a link to the fakes. The regional coroner reported that of the 11 deaths, the counterfeit medicine could not be ruled out as a cause for four of them. Also in 2005, the United Kingdom saw the recall of medicines from the legitimate supply chain when a counterfeit version of Pfizer's cholesterol drug Lipitor® (atorvastatin calcium) was found. The resulting nationwide recall of 120,000 packs of the 20 mg Lipitor involved 240 pharmacists. After analysis it was found that approximately 60% of all packs returned were counterfeit.

In 2003, 18 million repackaged Lipitor® tablets – a mix of counterfeit tablets and authentic tablets intended for non-US markets – were recalled from the legitimate supply chain. According to authorities, it was the largest recall of a prescription medicine in the U.S.

It is not just Pfizer whose medicines are being counterfeited. For example, counterfeiters have soaked the labels off vials of a low-strength version of Johnson & Johnson's anemia drug Procrit®, used by cancer patients—and affixed fake labels for the highest strength. And counterfeit vials of the human growth hormone Serostim®, used to treat severe symptoms of AIDS—have been discovered in New Jersey, Texas and Hawaii.

Weaknesses in the drug-distribution system, importation of medicines, the rise of Internet pharmacies, a weak economy, and reductions in health benefits all have contributed to the recent increase in counterfeiting.

The FDA, along with other organizations such as Pharmaceutical Research and Manufacturers of America (PhRMA), Health Distribution Management Association, (HDMA), National Association of Chain Drug Stores (NACDS) and state agencies are actively working to reduce the threat of counterfeiting.

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What are the causes of counterfeiting?

Technology to produce everything from labels to active pharmaceutical ingredients is now widely available.

Globalization has made distribution channels easy targets for introducing counterfeit products.

The Internet provides counterfeiters with ready access to consumers and markets.

Regulations governing the drug distribution system do not provide a strong enough deterrent, in terms of enforcement and penalties, to discourage counterfeiters.

Organized crime has become increasingly involved in counterfeiting as it becomes

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What are the consequences of counterfeiting?

Counterfeiting has significant social and economic consequences.

Most importantly, consumers don't get the safe and effective products they pay for and, instead, may be put at significant risk.

On the economic side, legitimate manufacturers of pharmaceuticals suffer from patent and copyright infringement. Counterfeiting, in reality, "hijacks" the brand.

Additionally, counterfeiters take full advantage of the fact that someone else paid the upfront money for research and development expenses; all counterfeiters have to do is to copy the product.

Governments lose as well. Huge amounts of resources are necessary to combat counterfeiting, there is also a negative affect on tax revenues. In fiscal year 2001, U.S. Customs seized over $57 million in counterfeited and pirated products, which represented a significant loss in taxes.

Additionally, health plans are being defrauded.

Counterfeiting is a "lose-lose" situation for consumers, governments, and legitimate manufacturers as well.

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What is Pfizer doing to combat the counterfeiting problem?

Pfizer continues to explore and implement new technological developments to deter counterfeiting.

The company uses special packaging and printing techniques that make counterfeiting both more difficult to accomplish and easier to spot.

Pfizer also has put in place business practices designed to 1) protect patient health, 2) increase cooperation with law enforcement agencies to successfully prosecute counterfeiters, and 3) promote proactive public policy that will help eliminate counterfeiting.

Pfizer is working with the FDA, wholesalers, the pharmacy community and others to determine how to best keep the American drug distribution system safe for patients.

Pfizer is working with wholesalers, the pharmacy community, and all regulatory and law enforcement agencies, such as the FDA, the British Medicines and Healthcare products Regulatory Agency (MHRA), the Australian Therapeutic Goods Administration (TGA), and others globally to determine how to best keep the drug distribution system safe for patients.

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What can be done to improve the situation?

Strengthen accountability within the drug distribution system through tougher enforcement and penalties.

Evaluate and improve, where necessary, the business practices of all those who distribute or dispense prescription medicines.

Employ new technology that has been proven to be effective against counterfeiting. Determine whether increased regulation is needed at both the state and federal levels. Evaluate whether the FDA will need additional resources to deter counterfeiting. FDA collaborative efforts with industry have been a very positive first step.

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What can you do to help?

Ask questions and express your concerns about drug counterfeiting, poorly repackaged products, confusing or foreign labeled packs, or any other issues regarding your medication that you do not feel confident in or would like more help from your pharmacist to explain and resolve. Do not leave the pharmacy if you are unhappy, concerned or confused about any aspect of your medicines, the way the medicine is packaged, or the condition of the medicine or packaging.

Consult your doctor or pharmacist and join a patient organization that represents your interests and seek advice from them on your medicine, how it should be packaged, its appearance, the effects of switching to generic or different formulations, and your rights to refuse any medicine you are not confident in or are confused about. Ask about your rights to your standard, long-term medicine packaging. Inform Pfizer in your country that you are not happy - as this allows us to let the authorities know that patients are also concerned.

Find the Pfizer location in your country

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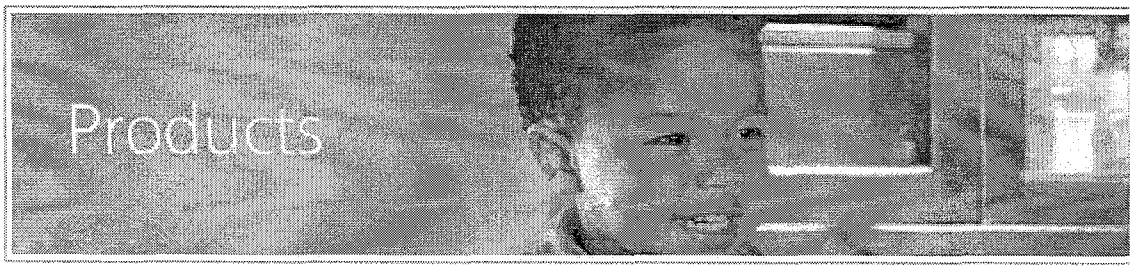

Helpful Web sites

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Below is a list of Web sites that provide more information about counterfeit and importation.

United States Web sites

Pharmaceutical Research and Manufacturers of America (PhRMA)—Organization that represents and advocates for U.S. pharmaceutical and biotechnology companies.

> BuySafeDrugs.info—PhRMA-sponsored clearinghouse for the latest news, policies, opinion, and research on prescription drug importation that also provides news alerts and information about alternatives to importation.
>
> Safemedicines.org—PhRMA program that provides the basics of medicine safety, precautions to consider when buying medicines online, and tips on how to avoid counterfeit medicines as well as a daily news digest and links to helpful safety resources.

United States Chamber of Commerce—World's largest not-for-profit business federation that, among other things, works to stop the spread of counterfeit products.

> The Coalition Against Counterfeiting and Piracy (CACP)—Coalition, co-chaired by the U.S. Chamber of Commerce and the National Association of Manufacturers, that is committed to increasing stakeholders' understanding of counterfeiting and piracy by working with the United States Congress and the Bush Administration to address this threat. Pfizer is a member of CACP's Legislative Committee and its International Committee.
>
> United States Chamber Counterfeiting and Piracy Issues Center—U.S. Chamber's global initiative to combat counterfeiting, includes recent anti-counterfeiting actions anc access to all counterfeit related site content.
>
> United States Chamber Intellectual Property Rights—U.S. Chamber's issue statement on counterfeiting and intellectual property rights (IPR), and access to all IPR related site content.

United States Department of Homeland Security (DHS)—Government department that

integrated agency focused on protecting the American people and their homeland.

National Intellectual Property Rights Coordination Center—Multi-agency Center responsible for coordinating a unified U.S. Government approach to IPR enforcement issues. Particular emphasis is given to investigating major criminal organizations and those using the Internet to facilitate IPR crime.

United States Customs & Border Protection (CBP)—Agency of the DHS responsible for managing, controlling and securing United States borders.

United States Department of Commerce (DOC)—Government department with the responsibility to foster, serve, and promote the Nation's economic development and technological advancement.

Strategy Targeting Organized Piracy (STOP!)—Initiative launched by the USPTO to combat the threat of counterfeit products. Includes a hotline as well as information to leverage the resources of the U.S. Government to secure and enforce trademarks, patents, and copyrights overseas.

StopFakes.gov—USPTO's Web site devoted to the STOP! initiative.

United States Food & Drug Administration (FDA)—Government organization responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation; advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

FDA: Combating Counterfeit Drugs—Outline of the FDA's efforts to combat the threat of counterfeit medicines and links to the FDA Counterfeit Report and a discussion of Radio Frequency Identification (RFID) feasibility.

FDA: Center for Biologics Research and Evaluation (CBER) Initiative Against Counterfeit Drugs—FDA's July 2003 CBER Initiative to address the increasing concerr about the possibility of potentially unsafe counterfeit drugs reaching consumers. Includes interim and final reports.

FDA: Center for Drug Evaluation and Research (CDER)—"Looks can be deceiving" consumer education initiative designed to teach people what they need to know before deciding to purchase medication outside the United States.

FDA: MedWatch—Timely safety information on drugs and other medical products regulated by the FDA.

FDA: Buying Medicines and Medical Products Online—Tips and warnings from the FDA for consumers buying medicines and medical products online.

FDA News: Drug Industry Daily Online—FDA's online news digest of pharmaceutical industry related news. **Updated daily**.

The Center for Medicines in the Public Interest (CMPI)—Clearinghouse of information on the development, accessibility, and safety of pharmaceuticals.

International Web sites

European Alliance for Access to Safe Medicines (EAASM)—An independent, cross-sector patient safety Alliance campaigning for the exclusion of counterfeit and

surrounding counterfeit medicines. Pfizer is actively involved as a key Alliance member helping drive initiatives against counterfeit medicines.

International AntiCounterfeiting Coalition (IACC)—International coalition of organizations committed to deterring counterfeiting and piracy worldwide.

International Chamber of Commerce (ICC)—Global business organization serving world business by promoting trade and investment, open markets for goods and services, and the free flow of capital. Get more information on ICC's IPR efforts. Learn more

> Business Action to Stop Counterfeiting and Piracy (BASCAP)—Initiative developed under the umbrella of the ICC. Created to leverage individual company and organizational efforts to urge action by governments and enforcement officials on counterfeit and piracy issues. Get additional BASCAP information. Learn more.

International Federation of Pharmaceutical Manufacturers (IFPMA)—Non-profit non-governmental agency representing research-based pharmaceutical industry associations from both developing and developed countries.

Interpol—World's largest international police organization that provides a range of essential services for the law enforcement community to optimize the international effort to combat crime, including counterfeiting and product integrity issues.

> The Third Global Congress on Combating Counterfeiting—Congress convened by Interpol and The World Customs Organization with the support and participation of the World Intellectual Property Organization with the objective to develop a collective understanding of the extent of the counterfeit problem and identify effective measures to combat it.
>
> The Second Global Congress on Combating Counterfeiting
>
> The First Global Congress on Combating Counterfeiting

Medicines and Health Care Products Regulatory Agency (MHRA)—United Kingdom agency committed to safeguarding public health by ensuring that medicines, health care products, and medical equipment are used safely and meet appropriate standards of safety, quality, performance and effectiveness.

Australian Therapeutic Goods Administration (TGA)—Australian government agency responsible for safeguarding public health and safety in Australia by regulating medicines and medical devices.

The Organization for Economic Co-Operation and Development (OECD)—Group of member countries that share a commitment to democratic government and the market economy and work on economic and social issues including development, science, and innovation. Learn more about the multi-year OECD project on counterfeiting and piracy.

Verified Internet Pharmacy Practice Sites (VIPPS)—List of certified online pharmacies that helps to ensure authenticity when buying prescription medicines online.

World Customs Organization (WCO)—Independent intergovernmental body whose mission is to enhance the effectiveness and efficiency of Customs administrations.

IPR)—Joint venture with international business sponsors that provides the world customs perspective on global counterfeiting issues and a full range of services for the benefit of its members and sponsors. Pfizer is a member.

World Health Organization (WHO)—United Nations specialized agency for health whose objective is the attainment by all peoples of the highest possible level of health as defined as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

WHO: Counterfeit and Substandard Medicines Homepage—WHO counterfeit and substandard medicines information, reports, and activities.

WHO: Substandard and Counterfeit Medicines Fact Sheet—Fact sheet that defines substandard and counterfeit medicines, their consequences, and actions necessary to address them.

WHO: Essential Drugs and Medicines Policy—*Counterfeit drugs: Guidelines for the Development of Measures to Combat Counterfeit Drugs* **brochure.**

German Pharma Health Fund E.V. (GPHF)—Initiative of research-based pharmaceutical companies in Germany that projects focus on quality control and quality-management activities in the area of drug supply, and on the improvement of basic health care. For specific counterfeit information, see the GPHF's report Counterfeit Medicines: An Unscrupulous Business.

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The Counterfeiting of Healthcare Products

The Issue

The counterfeiting of healthcare products represents an unacceptable threat to patients' welfare. It can also damage healthcare companies, not simply through lost sales, but also by involuntarily associating them with sub-standard and dangerous products. In the mid 1990s, the International Chamber of Commerce estimated that 7% of all world trade was counterfeit. Healthcare products are in high demand and easily transportable, and are therefore particularly attractive to counterfeiters, making this an issue of key importance to the industry and GSK.

GSK's Position

- GSK is a research-based company dedicated to fighting disease by bringing innovative medicines to patients throughout the world and to the healthcare providers who serve them. GSK is committed to the best possible standards of product quality.

- There is no such thing as a "good" counterfeit. Any counterfeiting of a healthcare product is unacceptable since the products have been manufactured and /or packaged outside the properly controlled channels.

- Fake medicines can kill people. They either poison them, or they do not help to cure or immunise them so they die of the disease they have or contract.

- GSK recognises that the pharmaceutical industry has a role to play in helping to minimise the counterfeiting of our products and is committed to a comprehensive programme of action against counterfeiting.

- However, GSK cannot tackle this issue alone. The prevention and detection of counterfeits is primarily a matter for national governments worldwide which must be encouraged to recognise the dangers associated with the practice and ensure its effective regulation by the relevant authorities.

- The dangers of counterfeiting are increasing in these days of globalised trade. The WHO has identified trade "involving several intermediaries and free trade zones" as a key driver of counterfeiting activity.

BACKGROUND

1. Definition

The WHO definition of a counterfeit product is "one that is deliberately and fraudulently mislabelled with respect to identity and / or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, the wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging."

2. The extent of the problem for Healthcare Products

Healthcare products are an attractive target for counterfeiting because they are a high value item in relation to their bulk, and a fake can be made relatively cheaply. For pharmaceutical products, counterfeits represent a peculiar danger because of the way in which they reach the consumer: the doctor who prescribes the product and is well informed about its efficacy rarely sees it, and the patient normally has little or no knowledge about the product or even his own medical condition to allow him to be a discerning consumer.

- Figures for the level of counterfeits are hard to establish. Because the activity is criminal and hidden from view, it is very difficult to measure. However, some estimates have been made:

- A WHO/IFPMA workshop on counterfeits in 1992 declared: "The Counterfeit Intelligence Bureau (a division of the International Chamber of Commerce) estimates that 5% of all world trade in 1991 was counterfeit. This is likely to be greater for pharmaceuticals which are in high demand and easily transportable. Estimates from a wide spectrum of countries range from 0% to over 60% in sectors of the market that are inadequately controlled".

- A WHO/IFPMA CEO roundtable on 3 November 1999 reported that the WHO Counterfeit Working Group has found that between 10-20% of drug samples in developing countries fail quality tests (and there is a wide variation between countries).

3. Adverse health effects of Counterfeits

- **Counterfeits can kill.** Fake medicines kill people. They either poison them, or they do not help to cure or immunise them so they die of the disease they have or contract. In these cases, counterfeit drugs can be more dangerous than narcotic drugs.

- **Counterfeits are never safe to use.** Counterfeit medicines are rarely as efficacious as genuine ones, and are not manufactured under the same strict conditions of quality control, safety and hygiene. Patients taking them are therefore exposed to unknown risks.

- **Counterfeits deceive patients**. Patients buying or being given counterfeit medicines are unlikely to know that what they have is not genuine and could be harmful. There is no question of a consumer making an informed decision to buy a fake medicine.

- **Counterfeits destroy confidence in healthcare systems**. Public confidence in pharmacists, doctors and nurses who unwittingly distribute counterfeit medicines, can be damaged by counterfeit medicines. Such a loss of confidence harms patients and the public as much as the health system.

4. Key drivers of counterfeiting

- **Monetary Gain.** The overriding reason for counterfeiting is the huge sums of money that can be made. Low manufacturing costs and high profits for fake medicines attract criminals who see their manufacture and distribution as an easy way to make money.

- **Lack of legislation and proper enforcement.** Where there is poor legislation controlling the manufacture, import and distribution of healthcare products, or a lack of enforcement measures, counterfeiters can easily escape detection and prosecution.

- **Weak national drug regulatory enforcement.** In countries where the enforcement of pharmaceutical legislation is weak, counterfeiters can remain unpunished.

- **Feeble penal sanctions**. The lack of, or lenient, custodial sentences for criminals who are convicted of counterfeiting – in contrast to harsher sentences for narcotic drug pushers – can allow counterfeiting to grow. Financial penalties are simply factored into overheads by counterfeiters.

- **Transactions involving many intermediaries**. Where medicines pass through many intermediaries, or there are several paper transactions, the opportunities for counterfeiters to insert their products into the system increases.

- **Free trade and deregulation**. Facilitating trade within and between countries (via, amongst other means, increased use of the internet) gives counterfeiters greater scope to introduce their fake products into official distribution channels. Consumers become used to seeing a variety of packs and so are less wary of what may in fact be a counterfeit.

- **Lack of cooperation between stakeholders.** If the drug regulation authority, customs authority, the police, the government, the health system and industry do not cooperate properly, then it is easier for counterfeiters to escape detection, arrest and penal sanctions.

- **Lack of political will.** Governments in some countries regard counterfeiters as legitimate employers of local labour and their exports as economic benefit.

- **Consumer ignorance.** Most consumers do not know that their medicine may be fake. Recognising a counterfeit product is usually very hard.

5. GSK's Response

GSK aims to protect patients worldwide from counterfeits of its products and in each case takes all appropriate steps to safeguard public health, including working with those government ministries and authorities that have responsibility for public welfare in the affected market. GSK rigorously investigates and where appropriate takes legal action against the manufacturers, distributors, retailers and other parties involved in counterfeiting our products. Furthermore, in countries where counterfeiting of our products is prevalent, the product and packaging incorporate features that discourage the manufacture of counterfeits and help detection. It is a condition of GSK business that wholesalers must report any offers to supply suspected counterfeit GSK products and to report, isolate and withhold from sale any such stock that is received. Procedures are in place to apply controls to the sale and disposal of GSK products, manufacturing equipment, packaging and other materials used in the production of GSK products. GSK also works in close co-operation with pharmacists, wholesalers and other pharmaceutical companies to ensure that suspected counterfeiters and their intermediaries are thoroughly investigated and, where appropriated, prosecuted.

6. External Partnerships

In June 1997, GSK joined the Pharmaceutical Security Institute (PSI), an industry-wide programme dedicated to countering the rapidly increasing trade in illegal and counterfeit medicines. Funded by the majority of research-based multinationals and operating under the auspices of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), the PSI's functions include the supervision of worldwide enquiries into counterfeiting, and liaison with law enforcement agencies in bringing the perpetrators to justice.

The effectiveness of these measures, however, will be limited if external agencies do not adopt adequate measures of their own. It is unacceptable for authorities to tolerate counterfeits simply because the products are close copies of the original without appearing to pose a hazard to health. GSK is therefore committed to working with the IFPMA, the WHO, national and international governments and other appropriate bodies to encourage co-ordinated action to create an environment hostile to counterfeiting.

GSK welcomes Article 61 of TRIPs which imposes obligations on WTO members to "provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale". Unfortunately, implementation of the article has not been universal, especially in developing countries, where counterfeiting is most prevalent. Stronger and more specific legislation is needed to allow for action against counterfeiting of products to be taken. Political will is needed to mobilise resources for implementation of effective countermeasures.

Effective regulation and political will, combined with industry's own commitment, will forge a successful partnership for the elimination of counterfeiting.

January 2004

Raising supplier standards in India

In 2003, we assessed a potential new supplier of active pharmaceutical ingredients in India. We conducted initial audits of the supplier's two facilities to assess whether it could supply GSK. The facilities scored 37 and 23 per cent, well below the GSK minimum of 50 per cent. However, rather than simply refusing to work with the supplier we made recommendations and agreed action plans on how the supplier could improve. We provided guidance and training to support them with progressing improvements. We also brought the supplier to our manufacturing facility in Jurong, Singapore, as an example of good practice.

Four years on, the supplier has achieved the minimum required standards to work with GSK. We will continue to monitor and support the supplier to ensure performance continues to improve.

Security of supply

Ensuring a continuous supply of high quality medicines is essential to the patients who depend on our products, as well as to the success of our business. It is vital that security of supply is not compromised at any stage of the distribution chain.

Strategy directors from each therapy area have overall responsibility for security of supply. Divisional heads meet our procurement teams every month to discuss any potential issues.

GMS (our manufacturing business) implements contingency plans for a list of 'medically critical' products. These plans are defined on a product by product basis but may include:

- Holding sufficient stocks of products, where the product has a long shelf life
- Holding sufficient stocks of active pharmaceutical ingredients
- Sourcing products from more than one location (known as 'dual sourcing')

We work with all critical suppliers to encourage them to implement their own contingency plans. In high risk countries we will set up joint ventures to ensure that we maintain control over the distribution chain. We have three global contracts for suppliers that deliver goods between GSK facilities and distribute products to market. We conduct regular high level operational reviews of these suppliers, which include security elements.

Counterfeiting

According to the World Health Organization (WHO), less than one per cent of pharmaceutical products sold in developed countries are counterfeit, but in the developing world this figure may be higher than 10 per cent, and up to 30 per cent in some countries.

Counterfeit drugs come in many variations, and may contain:

- None of the legitimate active ingredient
- The active ingredient in reduced or sub-therapeutic amounts
- A completely different and/or inappropriate active ingredient
- Impurities such as unapproved colourants or micro-organisms
- Packaging that falsifies the product description or expiry date

Most counterfeit drugs are not subject to quality control, hygiene standards, testing of ingredients, monitoring of product specifications or equipment. Counterfeiting is a threat to public health, potentially causing harm to patients and even death.

Our approach

We add anti-counterfeiting features to our product packaging. These include holograms, security seals, complicated background patterns that are difficult to photocopy or scan, as well as a wide variety of covert identifiers which are added using print technologies and sophisticated markers. These help us to identify counterfeits and gather evidence against offenders. Our Packaging Security unit in the UK carries out forensic examinations of all suspected counterfeit GSK product.

Our sales employees world wide also play an important role in helping to discover counterfeit products through continual observation of the local market place. Our Corporate Security department investigates every potential case of counterfeiting and uses internal and external investigators to collect information which we then assess and report to the relevant government authorities to set in motion official law enforcement action.

As well as removing fake products from the market one of our primary aims is to trace the products back to source, to shut down the manufacturers and their partners (for example the packaging printers). We provide training for regulatory authorities, such as the FDA in the US, law enforcement agencies and customs officers in many parts of the world.

GSK works very closely with the wider industry to investigate cases of counterfeiting and we also raise awareness with governments internationally, pressing for stricter laws and more severe penalties. GSK is also a founding member of the Pharmaceutical Security Institute, (PSI), which coordinates the information collection and investigation process within the international pharmaceutical industry. The PSI is influential in helping to shape anti- counterfeiting policy among national governments and international organisations. Together with the PSI, GSK is a major contributor to the WHO's internationally represented anti-counterfeiting working groups.

For many years, GSK has been working with the Chinese Public Security Bureau to help eradicate the trade in counterfeit medicines. During 2007, we supported a major investigation that resulted in the arrest of an organised counterfeiting syndicate in Guangdong and Anhui Provinces, and the closure of an 'underground' factory. A huge quantity of counterfeit *Heptodin* and *Panadol* tablets were seized, along with the products of other multinational companies. The total market value of the seized products amounted to 100,000,000 RMB, (£6,750,000). This market value did not include the vast quantity of raw materials and semi-finished products that were seized. The quality and sanitary conditions at the factory were appalling. Subsequent scientific analysis revealed that the factory had also been producing counterfeit *Zeffix* for international markets.

Ten defendants in this particular investigation have now been convicted of counterfeiting; the two principals were sentenced to seven and a half and five years imprisonment respectively. The remaining eight defendants were sentenced to terms of imprisonment ranging from 16 to 20 months. Fines were also imposed.

The dismantling of this counterfeiting network has had a significant impact on the supply of counterfeit *Heptodin*, *Zeffix* and *Panadol* to the GSK China and International markets.

Criminals also counterfeit our consumer products. For example in 2007, we discovered counterfeit *Sensodyne* toothpaste in the UK that had been manufactured using diethylene glycol, a toxic substance, in place of glycerol. GSK contacted the authorities and media to raise awareness of the issue, and how to identify the fake toothpaste. We traced the counterfeit product back to a factory in China which was shut down by the authorities.

Our performance

In 2007 there were 429 reported cases of counterfeiting of GSK products. These resulted in 71 raids, 127 arrests with £15 million worth of counterfeit products found during raids.

The number of 71 raids includes seven criminal manufacturing facilities and 59 wholesale/distribution outlets. The seven factories represent criminal operations that were capable of mass production of counterfeit medicines and other healthcare products. The raids on these facilities undoubtedly prevented huge amounts of counterfeit product from entering legitimate markets around the world.

Anti-counterfeiting

	Number of reported cases of counterfeit	Number of raids	Number of arrests	Value of counterfeit products found during raids
2007	429	71	127	£15 million
2006	248	57	94	£10 million
2005	334	47	31	£13 million

Fair treatment of suppliers

It is important that we treat our suppliers fairly and pay them promptly. In some regions we conduct surveys to measure supplier satisfaction.

Improving speed of payment in the UK

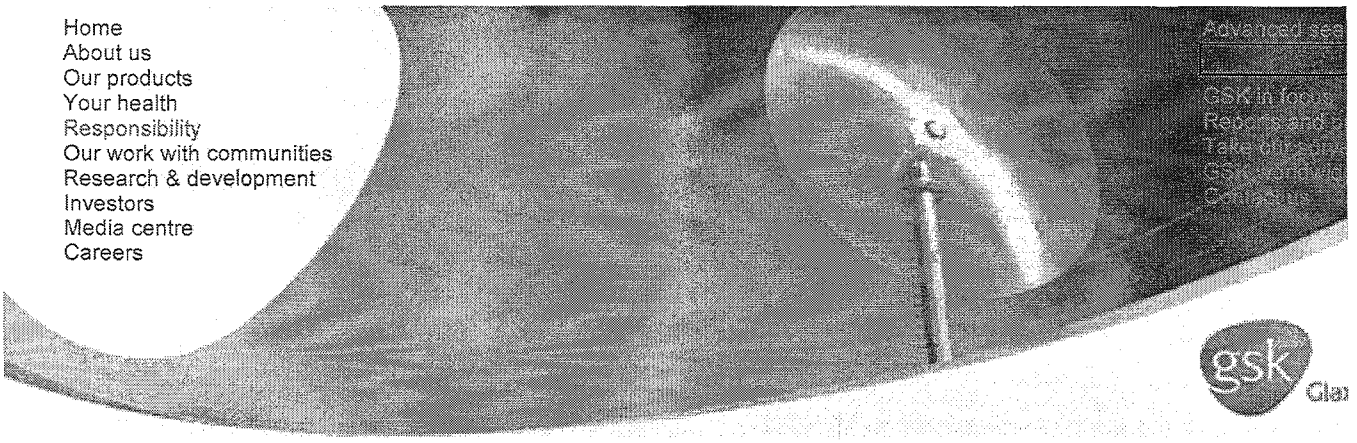
In 2007, we launched a programme to improve our performance for paying UK suppliers on time. In 2006, we paid around 75 per cent of suppliers on time. The main causes of late payment were: invoices being submitted on paper rather than through the preferred electronic system; invoices without a purchase order (PO) number; invoices submitted after the date on the invoice; and delays in the approval of invoice payment.

We worked with suppliers to encourage them to use the electronic system and to submit invoices on time. We also standardised payment terms for as many suppliers as possible, raised awareness about the use of POs and made the invoice approval process more efficient. This increased the proportion of suppliers paid on time to 83 per cent.

The future

We will continue to work with critical suppliers to help improve their EHS performance. This will include:

- Developing closer relationships with key suppliers through training and engagement
- Conduct business forums for suppliers to raise awareness of our standards
- Identify strategic suppliers to achieve 'Highly Protected Risk' status (high levels of engineering and fire protection standards)



Counterfeit products

Creations of the human mind are considered to be intellectual property. The ability of the creator to prevent someone else from using that intellectual property is defined by intellectual property rights law. Examples of intellectual property are patents, copyright and trademarks.

Healthcare products are an attractive target for counterfeiters as small volumes are valuable, and fakes are relatively cheap to make and easy to transport.

Fake pharmaceuticals may contain the wrong ingredients, have insufficient or no active ingredients, or carry incorrect patient information. They may not have been manufactured or packaged under properly controlled conditions. This means they are unlikely to be as effective as genuine products, and in the worst cases could be unsafe.

It is difficult to measure how much of the pharmaceutical market is taken by fake products. Estimates suggest that counterfeits account for more than 5% of all world trade in pharmaceuticals, and that this trade is worth billions of dollars each year.

We rigorously investigate any case of suspected counterfeiting and will take appropriate legal action against anyone involved in counterfeiting our products. We design our products and packaging to make counterfeiting difficult and to aid detection. Wholesalers are asked to report any offers to supply suspected counterfeit GSK products and to report, isolate and withhold from sale any suspect stock that is received. We pay particular attention to procedures for controlling the sale and disposal of products, manufacturing equipment, packaging and other materials to ensure that these cannot be used for the production of counterfeits.

We also work in close co-operation with pharmacists, wholesalers and other pharmaceutical companies to ensure that suspected counterfeiters and their intermediaries are thoroughly investigated and, where appropriate, prosecuted.

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NOVARTIS

Welcome to **Citizenship@Novartis**

Anti-counterfeiting

When questions of a medicine's authenticity are raised, patient confidence is eroded and the safety and efficacy of the treatment are uncertain. Novartis is committed to protecting patients against the doubts and dangers created by the proliferation of counterfeit medicines.

The integrity and reputation of our company depend on making every effort to assure healthcare professionals and patients that the products that bear our name are in fact Novartis products, backed by superior and unwavering standards of quality, safety and efficacy.

We are investing significant resources in a multi-pronged strategy aimed at preventing counterfeit Novartis medicines from entering the global supply chain and pharmaceutical marketplace.

While estimates vary widely, it is generally agreed that the chances of purchasing a counterfeit product are negligible if patients obtain their drugs from legitimate and known sources in Europe, the US or Japan. On the other hand, the risk of receiving a counterfeit medicine greatly increases in developing countries, or in developed countries when patients use unconventional or unfamiliar sources, such as Internet pharmacy sites.

Most stakeholders agree that the problem is growing globally and vigorous actions must be taken to stem the tide. Counterfeits are found among branded and generic pharmaceutical products, as well as over-the-counter medications. They can include products with the correct ingredients, wrong ingredients, no active ingredients, insufficient active ingredients or fake packaging. Counterfeit products expose patients to serious health risks and are illegal.

Read our position on Counterfeit medicines.

November 2005

Counterfeit medicines

A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging. Counterfeit medicines represent a serious and growing problem for patients and pharmaceutical manufacturers alike. For patients, who are generally unable to distinguish between authentic and counterfeit products, the health risks are enormous. Solving the counterfeiting issue requires sustained commitment not only from national governments, but also the pharmaceutical industry and other healthcare stakeholders such as licensed pharmaceutical distributors.

Novartis Position

Novartis is committed to working with national governments to prevent and prosecute the production or sale of counterfeit medicines. This is a longstanding commitment that is consistent with our overall concern for the health and safety of patients who use our products, as well as for the public health generally. The integrity and reputation of the Novartis brand depends upon on our ability to assure patients that products which bear our name are, in fact, our products, backed by superior, unwavering standards of quality, safety and efficacy.

Novartis is taking a diverse and multi-pronged approach to addressing the problem of counterfeit medicines. We investigate every reported case of counterfeited Novartis product, wherever it occurs, and maintain a global intelligence effort in order to identify, seize and destroy counterfeit Novartis products. We continuously monitor and improve the security of our distribution chain, as well as the security of the packaging of our products. We continuously apprise all Novartis companies of the dangers and complexities of counterfeiting; we actively participate in cooperative anti-counterfeiting efforts with groups representing our many industry and public health allies; we maintain an ongoing dialogue with health regulatory and law enforcement officials about the public health risks of counterfeit products and how they can be identified and seized; and we help governments develop and implement stronger laws, better enforcement and more severe penalties, and better public information.

NOVARTIS
caring and curing

Roche

Public Global Roche Statement on Counterfeiting

Counterfeiting of pharmaceutical and diagnostic products constitutes a significant public health issue worldwide. It is an increasingly common crime that, in addition to infringing intellectual property rights:

- endangers the lives and the well-being of patients;
- undermines confidence in healthcare systems and health professionals;
- creates a financial burden on patients and governments because of the money
- wasted on counterfeits and related enforcement measures;
- damages public confidence in authentic pharmaceutical and diagnostic products and
- their manufacturers and distributors, adversely affecting these legitimate businesses.

National authorities and agencies, such as health authorities, customs, police, intergovernment agencies, and international organizations (e.g. WHO), take the primary responsibility for the prevention and control of counterfeiting. Roche fully supports governmental efforts and is committed to cooperate with the authorities whenever a Roche product is concerned. However, Roche has no official power to intervene directly and will not assume liability for damage claims related to counterfeit products. Roche's policy ensures an action plan for rapid information, possible detection, coordination, analysis of suspect products, reporting and timely interaction with authorities.

To date, Roche's exposure has been low; only a few cases of counterfeiting involving Roche products have been discovered. Based on its corporate principles and recognizing the potential impact of this public health issue, Roche has further developed its policy for preventing counterfeiting and responding to counterfeit products within ist sphere of influence. As appropriate, Roche follows relevant national and international standards, guidelines and regulations aimed at combating counterfeit active pharmaceutical ingredients (APIs), medicines and diagnostics.

Counterfeit medicines are mostly offered for sale by unlicensed sources. The implications for public health and safety mean that Roche takes this issue extremely seriously. Roche discourages the buying of prescription medicine via non-authorized sources, such as not authorized Internet sites.

Roche has implemented technical anti-counterfeiting measures for some products. Current or future anti-counterfeiting measures cannot protect against all counterfeit medicines; sophisticated counterfeiters can detect and replicate anti-counterfeiting measures. On a case by case basis, incorporating requirements from authorities, Roche will pursue and coordinate anti-counterfeiting measures relating to the design, including packaging and labelling, of products that are subject to counterfeiting or that may have a high probability to become subject to counterfeiting. Despite these measures, consumers may not recognize a counterfeit of legitimate product, even with sophisticated anti-counterfeit measures.

This statement was approved by the Corporate Sustainability Committee in May 2006.

Product security

Ensuring the security of our medicines throughout their manufacturing and supply is another core priority for AstraZeneca. As part of this commitment, we are working to combat the growing problem of counterfeit drugs which have the potential to affect the health and wellbeing of millions of people worldwide.

WHAT TO DO IF YOU HAVE A CONCERN

AstraZeneca urges patients and healthcare professionals to be alert to the possibility of counterfeiting. Patients can protect themselves from the risks associated with counterfeit drugs by obtaining all prescription and over-the-counter medications from regulated licensed pharmacies. They should be vigilant when examining their medications, paying attention to altered or unsealed packaging or changes in the product packaging. Patients should be especially vigilant with products obtained on the internet because their origin and quality cannot be guaranteed.

If you have a concern, you should contact your physician, pharmacist or other healthcare professional.

The World Health Organization (WHO) defines a counterfeit medicine as one that is deliberately and fraudulently mislabelled with respect to identity and/or source. Whilst the full extent of counterfeiting is difficult to quantify, the problem is worldwide and particularly prevalent in developing countries. WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT) estimates that approximately 10 to 30% of medicines in emerging economies are counterfeit, with parts of Latin America, Asia and Africa even greater than that. By contrast, in countries with effective regulatory systems, counterfeits represent less than 1% of the market.

The potential dangers

Counterfeiting, which can apply to both branded and generic medicines, means that a product is deliberately and fraudulently labelled in a way that suggests that it is the authentic, approved medicine made by the genuine manufacturer. Counterfeits may include products made:

- Without the active ingredient
- With an insufficient or excess quantity of the active ingredient
- With the wrong active ingredient
- With fake packaging
- With incorrect labelling or administration instructions

Counterfeit drugs therefore pose many hazards to patients because they may:

- Contain the wrong ingredients or improper doses of the correct ingredients
- Contain inert substances instead of active ingredients
- Contain harmful ingredients
- Convey incorrect patient information, which could result in incorrect use
- Be genuine but out-of-date or expired products

Counterfeit drugs are unlikely to be as effective as genuine products. A patient who takes a counterfeit medication may be at risk from a number of dangerous health consequences. Patients may experience allergic reactions, unexpected side effects, or a worsening of their medical conditions. In the worst cases, these drugs could cause serious harm or even death.

Our commitment

Whilst the counterfeiting of medicines is a complex problem with no single or absolute solution, we have a range of activities focused on protecting patients. These include:

- Using technologies that make our products easier to identify and more difficult for counterfeiters to copy
- Monitoring market and supply chain activities to identify potential counterfeiting operations
- Working with supply chain partners to address product security issues
- Supporting increased awareness and education for patients and healthcare professionals

Alongside this, we continue to work with governments, regulatory authorities, law enforcement agencies and trade associations in efforts to ensure a secure drug supply chain.

We take immediate action when counterfeit AstraZeneca products are suspected. Suspected counterfeit samples are sent for analysis and authentication, and internally a global issues management team is convened. This team can comprise representatives from the local Marketing Company, Security, Legal, Quality Control, Medical, Regulatory, Supply, and Communications.

We are committed to the vigorous pursuit of anyone who makes, distributes or sells counterfeit versions of our products and we will seek prosecution of offenders to the fullest extent of the law.

We continue to explore other measures for combating counterfeit medicines and participate in a range of anti-counterfeiting public/private sector forums, including IMPACT and the Pharmaceutical Security Institute.

In 2007, AstraZeneca in the UK was alerted to an incident of counterfeiting of one of our anti-cancer medicines, *Casodex*. We worked with the UK Medicines and Healthcare Products Regulatory Agency to identify the counterfeit product and protect patient safety. Pharmacists, hospitals and dispensing doctors were given a dedicated AstraZeneca Customer Service number that they could call to discuss any concerns. We also ensured that our communications included a message to patients about what they should do. We continue to collaborate with law enforcement and regulatory authorities on their investigation of the incident and those responsible.

Protecting our medicines in transit

In 2007, AstraZeneca joined the Transported Asset Protection Association (TAPA). TAPA brings together global manufacturers from a range of industries, freight carriers, law enforcement agencies and other stakeholders with a common aim of combating supply chain crime.

Membership of TAPA complements our existing transport security arrangements and provides globally acknowledged standards for the protection of goods in transit by third parties. It also offers opportunities to share information and best practice with other manufacturers, the freight industry and key law enforcement partners in the countries in which we operate.

The content of this page was externally assured by Bureau Veritas, February 2008

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Counterfeit Products

According to the World Health Organization, the prevalence of counterfeit medicines ranges from less than 1 percent in developed countries, to more than 10 percent in developing countries.

The safety and integrity of Abbott products is our highest priority, and we take the threat posed to public health by counterfeit products very seriously. Our Global Product Protection department works to reduce the level of counterfeit copies of Abbott products entering the market. In 2006, our activities included:

With Abbott's help, authorities led more than 150 raids, executed 125 arrests, and obtained 40 convictions of individuals involved in the counterfeiting or theft of our products.

Securing Our Supply Chain

We audited 18 wholesalers in the United States for compliance with our Exclusive Sourcing Agreement, which requires wholesalers to purchase our products directly from Abbott and to sell only to authorized end users. We also expanded implementation of these agreements in Latin America and Asia and conducted supply chain reviews with our operations in Peru, Chile and Thailand.

Exclusive Sourcing Policy

Disrupting Criminal Organizations

Authorities led more than 150 raids, executed 125 arrests, and obtained 80 indictments and 40 convictions of individuals involving counterfeiting, illegal diversion or theft of Abbott products. Additionally, we conducted random purchases of various Abbott products in 30 countries to determine the level of counterfeiting and/or diversion. Some highlights of these activities include:

- In the United States, we recovered more than $3 million worth of our diabetes test strips and glucose meters that had been stolen in 2005.
- In Taiwan, authorities conducted a raid and seized nearly 300,000 capsules of counterfeit Reductil. Nearly 150 kilos of related raw material, machinery and packaging material were also recovered during the retrieval, as well as products from other pharmaceutical companies. Four individuals were arrested as part of this action.
- In Ecuador, after an investigation of counterfeit Dayamineral being sold in the marketplace, nine raids took place, resulting in the seizure of 626 bottles of product and 5,000 counterfeit labels. One arrest was made.
- Working in concert, U.S., U.K. and Hong Kong law enforcement authorities arrested a Shanghai-based wholesaler of counterfeit pharmaceuticals for worldwide trafficking of counterfeit Reductil and other products.
- In Brooklyn, New York, we identified and suspended a customer that was reselling diagnostic products to an unauthorized wholesaler.

Ensuring Our Ability to Authenticate

Authentication of our products is a key deterrent to counterfeiters. Our packaging strategy is to implement visible and non-visible security features on various packaging materials, on many of our existing products, as well as on new products as part of the research and development process. These security features facilitate authentication of Abbott products when suspected counterfeits are sent to our regional testing centers.

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Bristol-Myers Squibb Patient Assistance Foundation, Inc.

Fighting AIDS in Africa

Bristol-Myers Squibb Foundation & Corporate Philanthropy

Product Integrity

- Q & A on Counterfeit Products
- Authorized Distributors of Record
- Medicines (PDF)

Sustainability: Our Plan for Responsible Growth

Environment, Health & Safety Policy

Medical Education Grants And Charitable Contributions

Clinical Outcomes And Research Grants

Position On Key Issues

Product Integrity

Still have questions? We have Answers: Q & A on Counterfeit Products

1. What is a counterfeit product?
2. Why can counterfeit products be dangerous?
3. How do I know if I have a counterfeit product?
4. What can I do to help/protect myself from counterfeit products?
5. How can I best protect myself when filling my prescription online?

1. What is a counterfeit product?
The World Health Organization (WHO) defines a counterfeit medicine

A medicine which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging[1].

2. Why can counterfeit products be dangerous?

Counterfeit products are not authentic approved products. For this reason, consuming them may be dangerous because they may contai little to no active ingredient (the medicine that makes the drug work) and may not deliver the therapeutic benefit that the patient needs. O the other hand, counterfeit products may contain too much active ingredient, which could also be dangerous to the patient's health. Furthermore, counterfeit products may contain harmful ingredients ai may be contaminated because they are often made in substandard, unregulated, and/or unsanitary environments with no concern for safety.

3. How do I know if I have a counterfeit product?

Consumers may not know that they have received a counterfeit prod because counterfeiters attempt to mimic authentic product. For this

reason, it is important to purchase your products from a reputable distributor whom you know and trust. Understanding the source from whom you are obtaining your product is the best way to ensure the safety of your product.

To find out more about the product you are using you may refer to th Physicians Desk Reference (PDR) at http://www.pdrhealth.com/drug_info/index.html.

If you suspect that you may have received a counterfeit BMS product contact the source from which you obtained the product, the prescrib physician, or BMS at 1-800-321-1335.

4. What can I do to help/protect myself from counterfeit products?

Know your product, evaluate your product and packaging carefully. Check the color, texture, taste, shape and packaging each time you g your prescription filled.

Make sure that you understand the source from which you obtained your medicine, such as a licensed pharmacist or pharmacy.

Ask for your medicine in the product manufacturer's original packagir if possible.

If you suspect that you have received counterfeit BMS product contac the source from which you obtained your product, your prescribing physician, or BMS at 1-800-321-1335.

Educate yourself! Now that you are aware of the issue you have the power to protect yourself from counterfeit products, but your educati shouldn't stop here. The following links will take you to other sources more information on this issue:

- Food and Drug Administration's website regarding "Combating Counterfeit Drugs": http://www.fda.gov/counterfeit
- Partnership for Safe Medicines' web site: http://www.safemedicines.org/
- Buy Safe Drugs: http://www.buysafedrugs.info
- PhRMA Safety: http://www.phrma.org/safety/

5. How can I best protect myself when filling my prescription online?

When filling prescriptions online be sure that you see your doctor and obtain a written prescription beforehand. When buying over the internet, the U.S. Food & Drug Administration cites the following step to ensure the safety of your product:

- Check to see if a pharmacy is licensed and in good standing in t United States. Contact your local state board of pharmacy or th National Association of Boards of Pharmacy (NABP) at http://www.nabp.net or call 1-800-847-6227[2], or

- Check to see if an Internet pharmacy site has the VIPPS Seal, t seal of the Verified Internet Pharmacy Practice Sites Accreditati Program. This program was established by the NABP to help protect you and guide you through Internet pharmacy shopping Legitimate pharmacies that carry the VIPPS Seal are listed at http://www.nabp.net/vipps/consumer/listall.asp[2]

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[1]World Health Organization: General information on counterfeit medicines. http://www.who.int/medicines/services/counterfeit/overview/en/

[2]U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Counterfeit Medicines – Filled With Empty Promises: You can avoid counterfeit medicine by purchasing c from U.S. state-licensed pharmacies. http://www.fda.gov/cder/consumerinfo/counterfeitDrugsNAPS.htm

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Counterfeit Drug

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Information on Aranesp® Phase 3 Study in Cancer Patients
PRCA Update
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R&D Vision
Reimbursement Connection®
Medical Information
Pharmacy Affairs

Counterfeit Drug Statement

Amgen takes the issue of counterfeit drugs very seriously and is committed to the highest standards of drug quality and patient safety. Counterfeits by their nature are of unknown safety and efficacy, thereby putting patients at risk.

Our brand protection program supports an effective, secure, and resilient global supply chain, and the overall integrity of Amgen's medicines, for the protection and safety of our patients. Some of the measures Amgen is employing to deter, detect, and disrupt the criminal counterfeiting of our medicines include:

- Employing sophisticated technology to hamper the ability of counterfeiters to create packaging that resembles Amgen's.
- Requiring wholesalers to buy only directly from Amgen, and auditing compliance with these purchasing practices.
- Partnering with federal and state law enforcement agencies to investigate and prosecute those involved in product tampering and counterfeiting, facilitating the arrest and conviction of counterfeiters.

Amgen supports the use of appropriate track-and-trace techniques to advance the security of the supply chain and protect its products and patients and is collaborating with the FDA and industry partners to develop appropriate RFID implementation requirements. However, due to unresolved concerns about the effectiveness and feasibility of RFID technology, Amgen opposes the imposition of RFID requirements for biologics at this time.

Amgen assisted the Pharmaceutical Research and Manufacturers of America (PhRMA) with the development of PhRMA's voluntary program to report counterfeit drugs to the FDA. Amgen participates in the program, designed to assist the FDA in carrying out its responsibilities to protect the public's health by removing counterfeit drugs from the marketplace. Upon receipt of credible information concerning distribution of any counterfeit Amgen product, Amgen will inform the FDA in an effort to further help the agency take swift enforcement action.

Amgen's mission is to discover, develop and manufacture medicines that dramatically improve people's lives. Amgen's FDA-approved products have been proven safe and effective pursuant to FDA standards for use within labeling instructions, and have helped millions of patients facing grievous illnesses. Amgen's brand protection program supports this mission.

For additional information about drug counterfeiting, visit:

BuySafeDrugs.info
SafeMedicines.org
FDA anticounterfeiting portal
June 2006 FDA counterfeiting update

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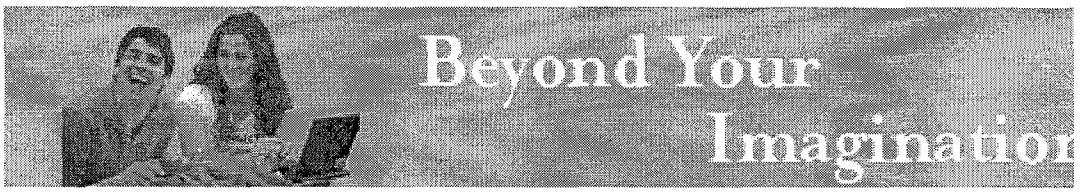

BUSINESS

Drug Giants Including Pfizer Seek Anti-Counterfeit Effort

By JAY AKASIE
Special to the Sun
March 4, 2008

With counterfeit prescription medicines flooding the world's markets, pharmaceutical giants are calling for a treaty that would set a first-ever protocol for fighting global piracy and counterfeiting operations.

At a meeting of the International Chamber of Commerce in Midtown yesterday, Pfizer, General Electric, and Sanofi-Aventis came together to discuss the proposed Anti-Counterfeiting Trade Agreement, which is largely aimed at combating what has become the most lucrative type of piracy around the world: fake prescription drugs.

According to the International Chamber of Commerce, global industry will lose an estimated 10% of its revenues to counterfeiting and piracy operations this year.

"This goes beyond just selling fake goods," Pfizer's senior vice president for pharmaceutical operations, Andreas Fibig, said at yesterday's meeting. "Counterfeit medicines place human lives at risk. This is now a public health issue."

Counterfeit medicines are taking a toll on New York City-based Pfizer, with global authorities over the past four years seizing some 33 million fake Pfizer tablets and enough ingredients to manufacture an

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additional 55.6 million tablets. As of last December, authorities have discovered counterfeit versions of Pfizer drugs such as Lipitor and Viagra in at least 75 countries. Counterfeits of seven Pfizer drug brands have turned up in legitimate supply chains in at least 25 countries.

Mr. Fibig was joined yesterday by the vice chairman of GE, Robert Wright, and the chairman of pharmaceutical firm Sanofi-Aventis, Jean-François Dehecq. The U.S. trade representative, Susan Schwab, met with the executives earlier yesterday morning and agreed to move forward with efforts to ratify ACTA by the end of this year.

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Previous page : Drug counterfeiters changing tactics to bypass EU customs

Drug counterfeiters changing tactics to bypass EU customs

by Emilie Reymond

16/11/2006- **Drug counterfeiters are changing their trafficking tactics to smuggle fake drugs into Europe.**

According to new data released by the European Commission last week, in 2005, 148 counterfeit drug shipments were stopped at the EU borders, with three quarters of them originating from India.

With these statistics, it would appear on the surface that India has become a hub in the traffic of fake drugs. Interestingly though, India was only the origin of one per cent of the total amount of fake medicines seized - in terms of quantity, Indonesia is leading the way with 16 per cent of the 500,000 fake drugs seized originating there.

Furthermore, last year's statistics show that there has been an increase in the number of incidences of fake goods seized by European customs in general, however, the actual overall volume of goods seized has dropped.

"2005 is the first year a breakdown of this data for medicines has been made, so it is impossible to give a direct comparison with previous years, however it is clear that European customs have seen a shift in counterfeit drugs traffic with counterfeiters now splitting quantities of drugs and sending them via different routes," Maria Assimakopoulou, a spokesperson for the European Commission told **In-Pharmatechnologist.com.**

This scenario is typical of the way counterfeiters now operate to bypass new customs measures implemented to tackle the transport of fake drugs, she said.

"They now understand measures adopted by European customs and looking at last year's statistics, it seems that, as a result, they tend to send smaller quantities using new transit routes."

One striking example of this is Switzerland, which has become a new route now used by counterfeiters to ship fake drugs whereas it didn't appear in the statistics in previous years.

"Earlier this year, a shipment of 350 kg of fake pharmaceuticals, which were stopped in the UK, were originally dispatched from China transiting through the United Arab Emirates, and then UK with a final destination in the Bahamas," said EU Taxation and Customs Commissioner László Kovács to illustrate how complex the routing of counterfeits is becoming.

"The process is even more complicated because this was an Internet order placed from Canada."

Indeed, he warned that the increasing use of Internet to sell fake medicines increases the challenge customs face.

"Fake medicines remain one of the most dangerous forms of counterfeiting," he said.

According to Kovács, a wider range of products are now being targeted, including antibiotics, cancer drugs, anti-cholesterol tablets and even common items such as paracetamol. He said that Viagra, however, still remains the counterfeiters' favourite.

One further point of interest from the European Commission's statistics is that China, which has had a reputation of being the worst offender when it comes to exporting counterfeit medicines, doesn't seem to be heavy in the balance with only one per cent of the number of fake pharmaceuticals seized at the EU borders coming from the country.

This is despite the fact that China is believed to be the world's number one source of counterfeit drugs, in a market estimated by the World Health Organisation to be worth a staggering $35bn (€27bn) a year.

Meanwhile, in response to the European Commission's findings, the pharmaceutical industry has consequently and obviously expressed its concerns about the significant number of fake drugs sold in the EU, which is showing no sign of weakening.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) said that the growing phenomenon of fake medicines transiting in Europe was a global issue requiring collective actions.

"The scourge of counterfeit medicines reinforces the need to tightly secure the entire pharmaceutical supply chain in Europe as international traders take advantage of more open borders and new technologies to conduct their criminal business without any scruple for people's health," said Thomas Zimmer, chair of EFPIA's anti-counterfeiting working group.

"By all means, patients must be encouraged to purchase prescription medicines through authorised distribution channels only!"

Zimmer stressed that while national authorities and international organisations were responsible for the prevention and control of counterfeiting, the pharma industry had its role to play in tackling the spreading of fake drugs.

He also emphasised how important a role the manufacturers, repackagers, wholesalers, distributors and pharmacies had to play in the issue.

"As the originator of the product, the manufacturer has an obvious role to play in product authentication and supply chain control efforts with new technologies, track and trace initiatives, procedures for counterfeit prevention," Zimmer said.

Part of the solution might lie in advanced tracking systems, such as Radio Frequency Identification (RFID), which could solve the problem at the root by helping companies avoid counterfeit pharmaceuticals entering the supply chain.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: June 8, 2006

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

Margaret Glavin
Associate Commissioner for Regulatory Affairs

FROM: Andrew vonEschenbach, MD
Acting Commissioner of Food and Drugs

Thank you for submitting to me the Counterfeit Drug Task Force Report – 2006 Update. I strongly concur that increasing the safety and security of the nation's drug supply and protecting it from the increasing sophisticated threat of counterfeit drugs is critically important. I commend you and the rest of the Counterfeit Drug Task Force on your efforts in developing this report and its recommendations to further this goal. I appreciate the fact-finding efforts that the Task Force undertook, such as holding the February 2006 public workshop and soliciting public comment, to understand the issues and provide me with informed recommendations.

I endorse the report and its recommendations. This includes the recommendation not to further extend the stay and to issue a compliance policy guide (CPG) that discusses FDA's enforcement focus regarding pedigree requirements. Please move forward with these recommendations, pursuant to FDA's good guidance practice (GGP) process (21 CFR § 10.115), as appropriate.

Andrew C. von Eschenbach, M.D.

FDA COUNTERFEIT DRUG TASK FORCE REPORT: 2006 UPDATE

I. INTRODUCTION

This report is based on the work of the Food and Drug Administration's (FDA or Agency) Counterfeit Drug Task Force.[1] It is the third report issued by the Agency since 2004 to address FDA's and the private sector's response to the emerging threat of counterfeit drugs entering the U.S. drug supply. This report contains recommendations to FDA's Acting Commissioner regarding actions that the public and private sector can take to further speed the adoption of electronic track and trace technology and for the use of pedigrees in general, to increase the safety and security of the U.S. drug supply.

After discussing the background and public comment on the issues addressed in this report, we discuss our recommendations or conclusions regarding:

- The expiration of the stay of 21 CFR §§ 203.3(u) and 203.50;
- The extent to which electronic track and trace technology is being used across the supply chain for electronic pedigrees and the use of radio-frequency identification (RFID) for drug products in the drug supply chain; and
- Technical issues related to the implementation of electronic track and trace technology, such as mass serialization, universal and uniform pedigrees, data management, and privacy issues.

II. BACKGROUND

A. The Counterfeit Problem

Counterfeit prescription drugs are illegal, generally unsafe, and pose a serious threat to the public health. Many are visually indistinguishable from authentic drugs. As we stated in our first Counterfeit Drug Task Force report in 2004 (2004 Report),[2] we believe that counterfeiting is quite rare within the U.S. drug distribution system because of the extensive scheme of federal and state regulatory oversight and the steps taken by drug manufacturers, distributors, and pharmacies, to prevent counterfeit drugs from entering the system. However, we are concerned that the U.S. drug supply is increasingly vulnerable to a variety of increasingly sophisticated threats. We have witnessed an increase in counterfeiting activities and a more sophisticated ability to introduce finished dosage form counterfeits into legitimate drug distribution channels over the years.

B. The 2004 Counterfeit Drug Task Force Report & 2005 Update

In 2004, the Task Force issued a report outlining a framework for public and private sector actions that could further protect Americans from counterfeit drugs, including implementation of new track and trace technologies to meet and surpass goals of the Prescription Drug Marketing Act (PDMA).[3] This framework called for a multi-layer approach to address the problem and included the following measures:

- Secure the ***product and packaging***
- Secure the ***movement of drugs*** through the supply chain
- Secure ***business transactions***
- Ensure appropriate ***regulatory oversight and enforcement***
- Increase ***penalties***
- Heighten ***vigilance and awareness***
- International ***cooperation***

In order to implement these measures, the Task Force Report stated, among other things, that:

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- RFID is a promising technology as a means to achieve electronic pedigree (e-pedigree);
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007; and
- The effective date of certain regulations related to the implementation of the PDMA should be delayed until December 1, 2006 in order to give stakeholders in the drug supply chain time to focus on implementing widespread use of e-pedigree.

In 2005, the Task Force issued an annual update report (2005 Report)[4]. The 2005 Report assessed FDA's and industry's progress toward implementing the 2004 recommendations. In the 2005 Report, the Task Force found, among other things, that:

- Stakeholders had made significant progress in developing and implementing RFID during the previous year;
- FDA was encouraged by the progress stakeholders, standard-setting bodies, and software and hardware companies had made toward implementing an e-pedigree for drug products and that we were optimistic that progress would continue in an expeditious manner toward meeting FDA's 2007 goal of widespread use of e-pedigree across the drug supply chain;

- If it appeared that the 2007 goal would not be met, we planned to consider options for implementing the provisions of the PDMA rulemaking that are the subject of the stay; and
- FDA would identify what we could do to address obstacles to the widespread adoption of RFID.

C. 2006 Fact-finding Efforts: Public Workshop, Vendor Display, and Docket

As the Task Force continued to monitor the adoption and implementation of e-pedigree and electronic track and trace technology, we recognized that adoption across the U.S. drug supply chain was slower than originally anticipated. To determine whether widespread use of e-pedigree by 2007 was still feasible, and to solicit comment on the implementation of certain PDMA-related regulations, we held a public meeting on February 8 and 9, 2006.[5] Our objectives for the meeting were to:

- Identify incentives for, as well as any obstacles to, the widespread adoption of RFID across the U.S. drug supply chain and possible solutions to those obstacles;
- Solicit comment on the implementation of the pedigree requirements of the PDMA and the use of an e-pedigree; and
- Learn the state of development of electronic track and trace and e-pedigree technology solutions.

Over 400 people attended the public meeting. Forty-six presentations were made and 27 vendors participated in the vendor display.

Members of the drug supply chain, the technology sector, special interest groups, academia, health professionals, and consumers also filed sixty comments to the public docket that we opened as part of the public workshop.

In addition, we have been attending conferences, meeting with stakeholders, tracking the status of pilot programs, monitoring changes in and use of technologies, participating in standards development, and closely following other influences to remain up-to-date on the relevant issues.

This report is based primarily on information gathered from these fact-finding efforts. It contains our views on outstanding issues related to e-pedigree and RFID implementation, as well as recommendations for additional public and private measures to support our continuing efforts to further secure our nation's drug supply.

III. WHAT IS NEXT FOR PDMA IMPLEMENTATION?

What should FDA do regarding the stay of 21 CFR §§ 203.3(u) and 203.50?

Issue/Background

The PDMA as modified by the Prescription Drug Amendments of 1992 (PDA) amended the Food, Drug, and Cosmetic Act (the Act) to, among other things, establish requirements related to the wholesale distribution of prescription drugs. Section 503(e)(1)(A) of the Act requires that

> "...each person who is engaged in the wholesale distribution of a drug***who is not the manufacturer or authorized distributor of record of such drug *** provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction.)"

PDMA defines an authorized distributor of record as a wholesaler that has an "ongoing relationship" with the manufacturer to distribute the drug. However it does not define "ongoing relationship."

In December 1999, the Agency published final regulations (1999 final rule) (21 CFR part 203) related to the PDMA[6] that were to take effect on December 4, 2000. After publication of the final rule, the Agency received communications from industry, industry trade associations, and members of Congress objecting to the requirements in 21 CFR §§ 203.3(u) and 203.50. These provisions define the phrase "ongoing relationship" as used in the definition of "authorized distributor of record" (ADR), set forth requirements regarding an identifying statement (commonly referred to as a "pedigree"), and define the fields of information that must be included in the pedigree. Those objecting to the regulations explained that some secondary wholesalers may not receive pedigree information from their suppliers who meet the PDMA's definition of "authorized distributor" because the PDMA does not require authorized distributors to provide pedigree information. Without this information, they explained, secondary wholesalers would not be able to sell the drugs because they would be unable to pass a pedigree that met all the requirements of 203.50. Many secondary wholesalers are small businesses and expressed concern that their inability to meet the regulations' requirements would frustrate sales and drive them out of business.

Based on the concerns raised, the Agency delayed the effective date for those provisions until October 1, 2001[7] in order to reopen the comment period for the regulations and receive additional comments. In addition, the House Committee on Appropriations (the Committee) requested that the Agency review the potential impact on the secondary wholesale pharmaceutical industry and prepare a report to the Committee summarizing the comments and issues raised and the Agency's plans to address these concerns. The Agency's report, which

was submitted to Congress in June 2001 (2001 PDMA Report to Congress), concluded that we could address some of the concerns raised by the secondary wholesale industry through regulatory changes, but that some of the changes requested by the secondary wholesale industry would require statutory change.[8] Since submitting the report to Congress, FDA has continued to delay the effective date of these provisions.

In February 2004,[9] FDA again delayed the effective date of the particular provisions until December 1, 2006, because we were informed by stakeholders in the U.S. drug supply chain that industry would adopt electronic track and trace technology by 2007. When widely adopted, this technology could create a de facto e-pedigree that would document the movement of the drug from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, e-pedigree could meet the statutory requirements in section 503(e) of the Act.

In our 2006 fact-finding effort, we sought comment on whether to continue the delayed effective date, let the regulations go into effect, amend the 1999 final rule, or take other steps.

What We Heard

Most of the comments[10] to our February 2006 notice advised FDA to implement the regulations and let the stay expire. Some said the regulations should be implemented as currently written, without amendment. Others suggested amending the final rule to either 1) exempt the passing of pedigree along primary supply chain routes or the "normal chain of distribution," or 2) phase-in implementation, starting with requiring pedigrees for those drugs that are susceptible to counterfeiting and diversion, or 3) require a pedigree for "one forward-one back" in the distribution chain (as opposed to a pedigree that documents all prior sales transactions back to the manufacturer). A couple of comments suggested that we extend the stay in order to give industry more time to continue moving toward adoption of electronic track and trace technology and e-pedigree. A few wanted the stay to be extended in order to give time to amend the regulations. The amount of time requested for extending the stay varied from 5 years to indefinitely. We also received one citizen petition from a secondary wholesalers' trade association requesting that the stay be extended.

Some comments suggested that FDA work with Congress to eliminate the provision exempting the authorized distributor of record from having to pass a pedigree. They claimed that it was too confusing to recognize when a pedigree should or should not be passed.

Several comments asserted that implementation of the PDMA regulations would speed the development of new, less expensive ways to provide pedigree.

Discussion

We carefully considered several options and recommend that FDA no longer delay the effective date of §§203.3(u) and 203.50 past December 1, 2006. Regulations defining "ongoing relationship" and "authorized distributor of record" are scheduled to go into effect thereafter. In our 2006 fact-finding efforts, we gave stakeholders and the public ample opportunity to provide their input, but we did not hear the same arguments that we heard on previous occasions regarding why we should further extend the stay. Rather, this time, an overwhelming majority of the comments favored allowing the stay to expire.

The PDMA was signed into law in 1988. We believe that FDA can no longer justify delaying implementation of these regulations. In its 2001 PDMA Report to Congress, FDA shared the concerns that were raised regarding implementation of the regulations. By recommending implementation of the stayed provisions, we are supporting the law that Congress passed and has since retained. Furthermore, our extensive experience with counterfeit and diversion drug cases reveals that the secondary wholesale market is where much of the illegal activity occurs. Allowing the stay to expire will provide clarity in the drug supply chain regarding who is and is not an ADR, requiring those secondary wholesalers who may be involved in illegal activity to provide pedigrees. Continuing the stay would perpetuate the current confusion and further allow opportunities for counterfeit and diversionary practices to flourish.

We do not intend to put secondary wholesalers out of business. We continue to be sensitive to the concerns that they raised several years ago, even though we did not hear these concerns during our current fact-finding effort. Therefore, as explained below, we recommend that FDA take an enforcement approach that focuses on products most susceptible to counterfeiting and diversion, which should relieve some of the burden that secondary wholesalers might confront when these regulations go into effect.

Most of the comments we received in this fact-finding effort recommended that the regulations be implemented as is, while others advocated a phased-in approach, whereby the regulations would apply to a limited number of drugs at first. We agree that the regulations should be implemented as is. Many of the recommended changes to the pedigree requirements would require a change in the law. We believe that the regulations as currently written appropriately interpret and implement the PDMA, as Congress intended.

Although the regulations do not provide for a phased-in approach, we propose that FDA publish a Compliance Policy Guidance (CPG) before the stay expires that will contain a list of factors for FDA field personnel to consider in focusing their efforts when carrying out their duties in enforcing the law. We propose that these factors reflect a risk-based approach in which FDA uses its limited resources to focus on drug products that are most vulnerable to counterfeiting

and diversion. We do not propose the creation of a list of drugs that meet the criteria, but instead suggest that the CPG provide examples. However, we recommend that FDA not limit its enforcement to just those drugs that meet the factors. Rather, the factors would merely provide guidance for where our field personnel should target their enforcement efforts. The factors to consider for the enforcement focus may include drugs with a high value in the U.S. market, drugs with prior indicators (such as drugs that were involved in diversion cases or counterfeiting), and drugs that are easily counterfeited.

We believe that this CPG would be considered a Level 1 guidance under FDA's good guidance practice (GGP) regulations. (21 CFR §10.115.) Therefore, we recommend that FDA publish a draft version for public comment, evaluate the comments, and then publish a final guidance by December 2006.

We recognize that complying with the stayed regulations may require changes in business practices. Compliance may also require implementation of additional information technology systems to generate a pedigree. Each of these processes may take time to achieve. However, we note that, although the regulations at issue have been stayed since 1999, the fundamental statutory requirement to pass a pedigree has been in effect since PDMA was enacted. The regulations primarily serve to clarify who is an authorized distributor of record and what information a pedigree must contain. In addition, we believe that this report and the CPG we advocate herein will focus public attention on this issue such that any wholesalers who thought that they were not subject to the pedigree requirement will have adequate time to take appropriate steps to comply with the regulations.

Furthermore, many States have moved forward with their own pedigree requirements, which often contain requirements in addition to those in the PDMA. We are aware that stakeholders are preparing to meet these State requirements, both electronic (to meet California law) or otherwise. Consequently, they should be that much closer to meeting the federal PDMA requirements as well.

Recommendation:

- **We recommend that FDA not continue to delay the effective date of §§203.3(u) and 203.50 beyond December 1, 2006.**
- **We recommend that FDA issue a draft Compliance Policy Guide for public comment that would focus FDA's pedigree-related enforcement efforts on those drugs most vulnerable to counterfeiting and diversion.**

IV. WHAT IS THE STATUS OF ELECTRONIC TRACK AND TRACE ACROSS THE DRUG SUPPLY CHAIN?

A. What is the progress of the use of e-pedigree in the drug supply chain?

Issue/Background

In the 2004 Task Force Report, we said that adoption and widespread use of reliable track and trace technology is feasible by 2007. We stated that this would help secure the integrity of the supply chain by providing an accurate drug "e-pedigree," an electronic record documenting that the drug was manufactured and distributed under secure conditions. We particularly advocated for the implementation of electronic track and trace mechanisms and noted that RFID is the most promising technology to meet this need.

In our 2006 fact-finding effort, we sought comment on the progress of e-pedigree implementation in the drug supply chain to determine if the goals outlined in the 2004 Task Force Report would be met.

What We Heard

Several comments described completed and ongoing pilot programs for e-pedigree and their successful deployment of e-pedigree in a real-time production environment. Most pilot programs involved distribution with one manufacturer, one wholesaler, and, in some cases, one pharmacy. Many comments stated that e-pedigree can be achieved using either RFID or barcodes. A number of comments stated that standards for e-pedigree are complete and that interoperable software is available. A few comments from manufacturers of already-serialized products said that they have developed track and trace systems capable of providing an e-pedigree through existing internet technologies.

Most comments agreed that it was necessary to adopt mass serialization with unique identifiers on each package as an important step to facilitate e-pedigree, while some comments stated that it is not needed. A majority of the comments stated that although widespread use of e-pedigree is not far off, it is hard to predict when that might happen or set a new timetable or a new target date. However, many comments suggested that FDA set a specific date by which all products must have an e-pedigree, arguing that without a specific date progress toward adoption will continue to be slow. Some comments recommended that FDA establish realistic phased-in compliance dates for adoption of e-pedigree.

Discussion

In 2004, we were optimistic that widespread implementation of e-pedigree was feasible by 2007 because we were told by many stakeholders in the drug supply chain that this was a realistic goal. Although significant progress has been made to set the stage for widespread use of e-pedigree, unfortunately, this goal most likely will not be met. We will not issue a new forecast or target date for adoption

of e-pedigree because we do not have enough information to do so at this time. Most comments said that it is difficult to predict or designate a target date. We do believe that a timetable with achievable, realistic milestones is crucial to keep e-pedigree implementation on track. Therefore, we recommend that FDA continue to work with members of the drug supply chain to develop such a timetable.

We believe that members of the drug supply chain should be able to implement e-pedigrees in the very near future. We applaud those members who already are taking steps to implement an e-pedigree and States that have championed this cause, such as California. However, it is clear from our recent fact-finding efforts that the voluntary approach that we advocated in the 2004 Task Force Report did not provide industry with enough incentives to meet FDA's deadline. The mere "risk" of the PDMA regulations being implemented was not enough of an incentive. When PDMA was enacted, the state of technology was not as advanced as it is today, and, as a practical matter the industry could pass only paper pedigrees.

We understand the complexity in moving toward an e-pedigree and recognize that a hybrid approach using both paper and electronic pedigrees will be needed during a transition period. We continue to believe that RFID is the most promising technology for electronic track and trace across the drug supply chain. However, we recognize that the goals can also be achieved by using other technologies, such as 2D-barcodes. Based on what we have recently heard, we are optimistic that this hybrid environment of electronic/paper and the use of RFID/bar code is achievable in the very near future. We believe that efforts to ensure that hybrid pedigrees are secure and verifiable should be a priority consideration.

If legislation is considered in Congress related to e-pedigrees, we stand ready to provide technical assistance.

Recommendation:

- **We recommend that stakeholders work cooperatively to continue to expeditiously implement widespread use of electronic pedigrees across the drug supply chain.**
- **We recommend that FDA provide technical assistance if legislation related to electronic pedigrees is considered in Congress.**

B. What is the progress of the use of RFID on drug product packages?

Issue/Background

We sought comment on the implementation status of RFID, including a description of the obstacles to widespread adoption, an estimate of the timetable, the suggested role of FDA, and the incentives needed to promote adoption.

What We Heard

A majority of the comments agreed that RFID is the most promising technology for track and trace in the drug supply chain. We received many comments describing current obstacles to wider adoption of RFID, including:

- A lack of standards (for e-pedigree fields and format, data systems, international transmission standards, and hardware specifications);
- Privacy concerns;
- Concerns about the ownership of confidential business transaction data;
- Challenges in serializing all products;
- Concerns over the accuracy and speed of electronic devices and systems; and
- A lack of definitive data to determine how RFID will affect sensitive products (e.g., liquids, biologics).

Many comments stated that it is not possible to predict or estimate a timetable for widespread adoption of RFID, or stated that widespread RFID adoption is at least many years away. Some comments estimated that it will take up to 10 years. Many comments suggested that technical issues (e.g., adoption of standards, product/software development) would need to be settled before a more accurate timetable could be estimated. A number of comments suggested a phased-in approach for RFID adoption to provide industry sufficient time to explore all options. One comment from a stakeholder closely involved in the development of RFID technology stated that the FDA timeline for RFID adoption is technically feasible, that is, widespread adoption of RFID is feasible by 2007.

Comments noted that progress toward the full adoption of RFID technology is occurring, but that adoption is moving more slowly than previously anticipated. Several pilot projects have been conducted or are underway to test the feasibility of RFID deployment along the prescription drug supply chain, but data is limited.

Most comments said that FDA should not mandate or require the use of RFID in the drug supply chain. Instead, some comments said that FDA should continue to encourage the use of RFID. Many comments said that FDA should actively participate in, support, and facilitate RFID activities, especially those activities of groups working to establish RFID standards and implementation. In addition, many comments said that FDA should take a lead role in developing a public education program about the use of RFID technology on drug products.

Most comments said that incentives would help in the adoption of RFID across the supply chain. Only one comment said that no incentives are needed. Comments suggested the following incentives:

- Financial/tax incentives;

- Mandating mass serialization on drug products, but allowing industry to determine the most appropriate technology to ensure compliance;
- Statutory changes.

Discussion

We continue to believe that RFID is the most promising technology for implementing electronic track and trace in the drug supply chain and that stakeholders should move quickly to implement this technology. We appreciate the candid views and concerns that were shared with us during this fact-finding effort in identifying obstacles to implementation. Within this report, we have tried to address the issues related to those obstacles that are within FDA's purview.

Although we are encouraged by the efforts of GlaxoSmithKline, Pfizer, and PurduePharma in tagging their products, and the efforts of many other companies and wholesalers in exploring and piloting RFID, we are disappointed with the lack of overall progress across the drug supply chain. In the 2004 Task Force Report, we laid out milestones and goals for RFID implementation based on credible information that stakeholders gave us. Many of these milestones have not been met. The technology vendors uniformly told us that their RFID and e-pedigree solutions and technologies are ready to go, but manufacturers, wholesalers, and retailers are slow to implement them.

We recognize that progress may have been delayed because standards have not yet been established. However, we are encouraged by the progress that industry has made to develop and adopt universal standards. Based on what we heard, those standards are close to completion. Once completed, we would expect to see a rapid growth in the implementation of RFID in the drug supply chain. We look forward to continuing to participate and support this standards development process.

In November 2004, FDA issued a CPG for conducting pilot studies for RFID tagging. In that CPG, FDA excluded biological products as eligible for these pilot studies because we had insufficient information about the impact of radio-frequency (RF) on biologics. To date, we have not received sufficient information to change this policy. Therefore, the CPG continues to remain in effect as written until December 31, 2007. In order to further our understanding of the impact of RF, we have begun our own study to evaluate the potential impact of RFID on drug and biological products. We expect to share the results of this study later this year.

We recognize that implementing an RFID-enabled drug supply chain is challenging. We appreciate the comments advocating a phased-in approach and urge manufacturers to take a risk-based approach to implementation by first tagging the products that are most vulnerable to counterfeiting and diversion, based on factors such as the sales price, volume sold, demand, ease of

counterfeiting, and prior history of counterfeiting or diversion, among other things. If a company's products are not "at risk", then we would suggest the company choose its highest volume/highest sale drug(s) and start piloting. Although RFID deployment does have significant start up costs, based on our discussions and what we heard, most stakeholders agree that there are also significant benefits. Not only does the track and trace capability of RFID provide anti-counterfeiting and supply chain security benefits, but it also offers significant savings in the form of better inventory management, reduction in theft and product loss, improved recall efficiency, and reduced paperwork burdens.

RFID also has tremendous potential benefits for drug products used in public health emergencies, such as a pandemic influenza or a bioterrorist attack. RFID tracking could help in expeditious deployment and redeployment of medical countermeasures in times of crisis. FDA should, therefore, encourage manufacturers of these types of products to explore the use of RFID.

We agree with the comments that FDA should not mandate RFID. Although in 2004, we sought voluntary adoption and more widespread use by 2007, we believe that the private sector momentum is moving and that our input on some of the perceived obstacles may jumpstart further adoption interest and momentum. In the 2004 Task Force Report, we laid out a timetable for mass serialization and RFID implementation, as well as steps for businesses and standard-setting issues. Although the timetable goals were not met, we continue to stand by this approach and are prepared to work with stakeholders who wish to take the lead in developing a new, feasible, yet ambitious, timetable.

Recommendation:

- **We recommend that stakeholders continue moving forward in implementing RFID across the drug supply chain.**
- **We recommend that stakeholders consider a phased-in approach, placing RFID tags on products most vulnerable to counterfeiting and diversion as a first step.**
- **We recommend that FDA remain committed to facilitating RFID implementation and working with stakeholders, standards organizations, and others.**
- **We recommend that FDA work quickly to complete its RFID Impact Study examining drugs and biologics, and publicly share the results.**
- **We recommend that stakeholders explore the use of RFID for tracking medical countermeasures.**

V. WHAT TECHNICAL ISSUES RELATED TO ELECTRONIC TRACK AND TRACE NEED RESOLUTION?

1. Mass Serialization

Issue/Background

Mass serialization involves the incorporation of a unique identifier number on each drug package in order to track the individual drug package as it moves through the drug supply chain. We sought comment on mass serialization numbering schemes, including the preferred numbering convention, the merits of incorporating the National Drug Code (NDC) number and its impact on patient privacy, and the timetable for mass serialization across the drug supply chain.

What We Heard

Almost all the comments recommended that industry use a single numbering convention to reduce costs and complexity. One comment noted that multiple numbering schemes could lead to conflicts (e.g., duplicate numbers for the same item) and incompatibility between points in the distribution chain. Several comments suggested that using random numbers for the product identification component of the electronic product code (EPC) could increase security, while concealing proprietary information about the product or manufacturer. However, other comments suggested that the EPC should include the manufacturer ID as part of the code.

Many comments addressed whether or not the NDC should be included in the unique identifier. Many comments were concerned that RFID tags could be surreptitiously read, and if the NDC was included, it could jeopardize the privacy of patients and potentially endanger the drug supply chain. However, pharmacies and their trade groups supported the inclusion of the NDC, arguing that their information systems currently identify products by using the NDC and that they might incur significant costs to change these systems if they used an EPC that did not include the NDC. Some of these comments also noted that the NDC plays an important role in the dispensing process and it would be disruptive to workflow to have to consult another database to link the EPC number to the NDC number. However, a couple of the comments noted that it is not necessary to include the NDC as a component of the unique identifier because, pursuant to FDA regulations (21 CFR §§ 201.2 or 201.25), the NDC is printed on most drug packaging.

Finally, several comments from stakeholders that are closely involved in developing the EPC standards suggested that the numbering convention be sufficiently flexible to accommodate standards-based numbering systems already in use (e.g. NDC for pharmaceuticals, UID for U.S. Department of Defense, EAN.UCC for consumer goods.)

Discussion

We continue to believe that using mass serialization to uniquely identify all drug product packages in the U.S. is a powerful tool in securing the nation's drug

supply. The issues surrounding which numbers should be included in this unique identifier are complex. The NDC number is ubiquitous as an identifier of drug products for inventory, dispensing, and claims adjudication, among other things. However, because it is such a recognized number, an NDC number could compromise patient privacy and supply chain security if it could be read surreptitiously.

We believe that the NDC number is an important product identifier and it should be closely associated with the product. We note that, currently, for most prescription drug product packages, the NDC number is either printed on the packaging or included in a bar code on the package. We do not anticipate this practice to change.

We also recognize that inappropriate access to the NDC number on individual products raises patient privacy and security issues. These competing concerns, however, can be addressed through IT solutions. Therefore, we believe that for drug product packages using RFID or other non-line-of-sight technologies, the unique identifier should either include an encrypted NDC number or provide an accessible link to the NDC number that is readily available to pharmacies to facilitate their needs.

Ideally, there should be one numbering scheme used in the drug supply chain. We recognize that the technology continues to advance and it is difficult to predict what its capabilities will be in the near future.

Recommendation:

- **We recommend that the NDC number should continue to be closely associated with the product.**
- **We recommend that for non-line-of-sight technology, such as RFID, the unique identifier for the product should either include an encrypted NDC number or an accessible link to the NDC number to protect privacy.**

2. Universal Pedigree and Uniform Pedigree Fields

Issue/Background

The PDMA limits who is required to pass a pedigree and authorizes FDA to determine what information should be included in the drug pedigree. This information is codified at 21 CFR 203.50. Some States have laws imposing pedigree requirements on members of the drug supply chain not covered under the PDMA. Some States have enacted laws requiring additional information to be included in pedigrees passed with drugs sold in their State. In addition, State requirements differ with respect to the information that must be included in the pedigree. We sought comment on what information pedigrees should contain and how such a uniform standard could be achieved.

What We Heard

Nearly all comments encouraged FDA to implement federal uniform pedigree requirements and standards binding on the drug supply chain and States. Several comments noted the work of stakeholder initiatives, including the Uniform Pedigree Task Force and the EPCglobal e-pedigree standards working group. These stakeholder initiatives suggested data fields that could be captured in a uniform pedigree, including:

- Product Information: drug name, manufacturer, product NDC, dosage form, strength, container size;
- Item Information: lot number and expiration date, quantity of units by lot, product serial number (if serialized);
- Transaction Information: transaction identifier (e.g., PO, invoice) and date, transaction type (e.g., sale, transfer, return), date received;
- Trading Partner Information: business name, address and license of seller, alternate ship-from location of seller, seller contact information for authentication, business name, address and license of recipient, alternate ship-to location of recipient;
- Signatures/Certifications: digital signature of seller, digital signature of recipient.

There was near complete agreement that all wholesalers, not just non-authorized distributors, should be responsible for passing pedigree information. Many of these comments urged FDA to take appropriate steps to require a universal and nationally uniform e-pedigree so that stakeholders do not have to comply with 50 different State pedigree requirements.

Discussion

The PDMA requires a statement/pedigree ("in such form and containing such information as the Secretary may require") to be passed with certain wholesale distributions. The PDMA and FDA's pedigree-related implementing regulations define the information that must be included in a pedigree.

We continue to believe that a universal e-pedigree (i.e., a pedigree passed by all wholesalers, not just those who are not authorized distributors of record) that documents the movement of every prescription drug product from the manufacturer to the dispenser would be an important step in preventing counterfeit drugs from entering the drug supply chain.

We also agree with the comments that a single, national, uniform pedigree would be ideal to help ensure efficient distribution of safe and effective medicines. To be most effective and efficiently communicate chain of custody and other information about the drug product, it would be ideal if all members of the drug

supply chain passed a pedigree that was uniform across all States. Fifty different State pedigrees will no doubt create confusion in the marketplace and could stifle interstate drug trade. For example, the pedigree laws that were enacted in Florida, California, Indiana, and other States contain different requirements.

Under existing law, FDA lacks statutory authority to implement a universal and nationally uniform pedigree. If legislation is considered in this area, we stand ready to provide technical assistance.

Recommendation:

- **We recommend that FDA provide technical assistance if legislation in this area is considered in Congress.**

3. Data Management/Data Security

Issue/Background

For e-pedigree transmission to be successful throughout the drug supply chain, business partners at each point in the supply chain should be able to share information effectively and efficiently. The choice of data management practices and standards becomes an important one for all stakeholders. One issue that has been raised is whether the data/information should be stored in one central database or if a distributed approach (where each stakeholder's system exchanges information with other systems) should be used.

What We Heard

A majority of the comments advocated the use of a distributed database approach to data management. Many noted that a centralized database would be more costly, slower to implement, a threat to patient privacy, and could disrupt drug distribution if the database was unavailable or compromised for some reason. Comments suggested that secure peer-to-peer transactions would be possible under the distributed model. One comment suggested that data management be controlled centrally via a third party, contractually-managed by FDA.

A few comments suggested specific data security measures, such as pedigree documents having digital signatures to maximize document integrity, authentication, and non-repudiation. Some comments referred to existing data transmission standards used elsewhere, specifically Public Key Infrastructure, Federal Information Processing Standards, and the ISO/ICE standards 17799 or 12207. One comment noted that e-pedigrees could be authenticated electronically, using electronic verification of the digital signature and the signed transaction content for each transaction. One comment promoted the use of biometric log-on methods to improve security.

Discussion

It is vital that specific event information contained in the electronic pedigree be secure. We have no preference as to whether the data is housed in a central database or in a distributed scheme. Based on what we heard, it is our understanding that e-pedigree is technologically feasible with either model and even in a hybrid environment, where some data is stored in a central database while other data is distributed across company servers. We believe it would be most efficient to let the market and technology dictate how to best capture and access the data in e-pedigrees.

We do believe that it is essential that every entity in a drug product's chain of custody has access to the product's pedigree data all the way back to the manufacturer, in order to verify and authenticate the pedigree. It is also important for FDA to have access to the information in matters of suspect illegal activity.

Recommendation:

- **We have no preference whether a distributed versus central database is used, as long as every entity in the chain of custody for the product has access to information about that product all the way back to the manufacturer.**

4. Privacy Issues

A. Labeling/Disclosure/Education

Issue/Background

There is general concern that an unauthorized person might be able to read the information from an RFID tag on a drug without the possessor of the drug knowing it, possibly disclosing personally identifiable information or the name of the drug. We sought comment on whether privacy concerns are warranted and whether it is possible for an unauthorized person to read the information from an RFID tag on a drug once that drug is in the consumer's possession. If so, what type of information could be accessed? We also sought comment on how to make consumers aware that an RFID tag is on the drug package and the type of consumer education that would be needed as the use of RFID in the drug supply chain becomes more prevalent.

What We Heard

The majority of the comments indicated that privacy safeguards are needed. However, some pharmaceutical organizations said that patient privacy issues are

not a major concern because many of the prescriptions filled at pharmacies are not dispensed in the original bottles from the manufacturer; the prescriptions are instead placed in a consumer-size container, which would not have an RFID tag. Some comments cited concern about persons gaining unauthorized access to information about the type of drug being taken as well as personal identifying information. Several comments said that the RFID tag should not contain information that identifies the drug (e.g., NDC number). Instead, these comments suggested that the tag should contain a random serialized number so that anyone reading the tag would see only a meaningless number.

Many comments referred to the importance of consumer notice and choice and the use of fair information practices. Comments noted that notice of the presence of an RFID tag on a drug package should be clear, conspicuous, and accurate. Several comments indicated that one way to address the issue of consumer notice is to use a symbol on the package. There was uncertainty, however, as to where the symbol should be placed.

Some comments pointed out that many concerns about privacy are due to concerns about database security (i.e., once the data is collected from an RFID tag, how secure is the database where it is stored?).

The majority of comments said that consumer education is needed for the successful adoption of RFID across the drug supply chain. Many comments indicated that consumers should be informed of the benefits of RFID (e.g., how RFID can help secure the drug supply chain), as well as the risks associated with the technology (e.g., potential threat to privacy). According to some comments, consumers should also be educated about the options that are available for deactivating or removing the RFID tag. Most comments said that FDA, as well as experts in academia, industry, and patient and consumer groups, should be involved in developing education programs.

Discussion

Privacy issues are a real concern for consumers and FDA. These concerns will continue unless there is appropriate disclosure of the presence of an RFID tag on containers given to patients and sufficient education about the application, true risks, benefits, and vulnerabilities associated with RFID tags on drug products. This is no easy task.

Although we support the use of a statement or symbol to disclose the presence of an RFID tag on a drug product package, it is important that manufacturers work with FDA to develop an appropriate message or symbol. Most statements made on the labeling of prescription drug products are regulated by FDA and subject to agency pre-approval. We, therefore, recommend that manufacturers should work with FDA before choosing a statement or symbol to add to their product labeling.

We also are willing to work with stakeholders to develop a uniform statement or symbol that can be used to signal the presence of an RFID tag on a drug product package to use in educational campaigns. Such campaigns would help consumers to readily identify and understand the meaning of the statement or symbol.

We do not propose to issue guidance at this time regarding statements or symbols on drug product labeling to indicate the presence of an RFID tag.

Consumer education is necessary. Potential messages could include educating consumers about RFID, the benefits of its use for patient safety, the privacy risks, possible risks from RF emission, and deactivation and removal of the tag. We do not currently have the resources to lead educational efforts. However, we will work with manufacturers and other stakeholders in their efforts.

Recommendation:

- **We recommend that FDA work with manufacturers and other stakeholders in their efforts to develop appropriate messages, symbols, or statements for labeling of drug products and packaging that contains an RFID tag.**
- **We recommend that FDA work with private and public sector organizations in their efforts to educate consumers about RFID.**

B. "Turning Off" the RFID Tag

Issue/Background

Some people have suggested that the RFID tag should be "turned off" or deactivated before it leaves the pharmacy, or that patients should be given the choice of whether it is "turned off". We sought comment on the advantages, disadvantages, and feasibility of deactivating the tag.

What We Heard

Many comments indicated that deactivating or removing the RFID tag at the point of purchase (i.e., the pharmacy) would effectively address privacy concerns. However, some comments pointed out that while deactivating or removing the tag would address privacy concerns, it may also prevent post-sale benefits (e.g., recalls) which would have been possible had the tag remained active/in place.

Some pharmacy groups said that the tag should be deactivated prior to arrival at the pharmacy retailer to ensure that no patient is inadvertently sent home with an active tag. One comment said that in practice, deactivating the tag at the point of sale is not feasible because it would place too much responsibility on pharmacists and may re-expose the drug to unknown radio-frequency effects.

Some comments indicated that FDA should provide guidelines to ensure privacy protections through RFID tag deactivation or removal.

Many comments suggested various deactivation methods. Some of the suggested options were: kill function (total or partial), blocker chips, encryption, read protection, decommissioning with individual tag password, tag destruction, placing RFID tagged objects in a foil lined bag (which would prevent unwanted reads), and database controls. There was no consensus on the best deactivation method. However, a standards organization commented that it is evaluating tag deactivation, taking into consideration the consumer and industry benefits of post-sale uses of RFID tags. The point in the supply chain where RFID tags should/could be deactivated is also being evaluated.

Discussion

There are benefits to both keeping the RFID tag active after sale and deactivating it before dispensing the product. We believe that an active tag can provide valuable information if the drug product finds its way back into the drug supply chain. FDA has found counterfeit and diverted drugs in the drug distribution system when drug wholesalers, third-party return entities, or manufacturers return drugs for credit and/or destruction. Those products with active tags would be easier to identify and track through the supply chain. That said, we respect the privacy concerns, however, and do not believe that it is necessary for an active tag to go to the patient.

It is unclear whether technological methods to deactivate the tag in the normal course of business are mature enough for use in the marketplace at this time. We believe that this issue warrants further discussion among stakeholders, technology experts, and consumers, about the viable options and we are not prepared to make a recommendation at this time.

Recommendation:

- **We recognize that this is an important issue, but do not have sufficient information to make a recommendation at this time.**

V. CONCLUSION

FDA's vision of a safe and secure drug supply chain is premised on transparency and accountability by all persons who handle the prescription drug, starting with the manufacturer and ending with the pharmacist who hands the drug over to the patient. Drug supply chain efforts that capitalize on advances in electronic track and trace technology to create a secure electronic pedigree further this vision.

With the implementation of the PDMA regulations in December 2006, we expect that supply chain stakeholders will move quickly to adopt electronic track and

trace technology, implementing RFID in a phased-in approach. We recognize that there are important issues that still need resolution, such as privacy concerns and uniform and universal pedigrees that might benefit from further discussion by stakeholders or Congress. However, these issues should not hinder the forward progress and momentum toward widespread adoption that we have witnessed and expect to continue. Companies should continue to tag drug products, build infrastructure across the supply chain for using an e-pedigree, and remain vigilant in their responsibility to provide a safe and effective drug product to the patient.

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[1] The Task Force consists of senior staff from the Office of the Commissioner (Office of Policy and Planning, Office of the Chief Counsel), Office of Regulatory Affairs, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research.

[2] The FDA Counterfeit Drug Task Force recommendations are detailed in its report, entitled, "*Combating Counterfeit Drugs – A Report of the Food and Drug Administration*," February 18, 2004 (2004 Counterfeit Drug Report) (http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html).

[3] PDMA (Public Law 100-293) was enacted on April 22, 1988, and was modified by the Prescription Drug Amendments (PDA) (Public Law 102-353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 333, 353, and 381) to, among other things, establish requirements related to the wholesale distribution of prescription drug products.

[4] *Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update*, May 18, 2005 (http://www.fda.gov/oc/initiatives/counterfeit/update2005.html).

[5] The workshop agenda, speakers' presentations, and meeting transcript are available at www.fda.gov/rfidmeeting.html .

[6] 64 FR 67720.

[7] 65 FR 25639.

[8] See http://www.fda.gov/oc/pdma/report2001/

[9] 69 FR 8105.

[10] In this report, the term "comments" includes comments that we heard at the public meeting and written comments submitted to the docket.

Attachment 2

Proposed Federal Standards for a Standardized Numeric Identifier and Technologies for Prescription Drug Identification

EDMUND G. BROWN JR.
Attorney General

State of California
DEPARTMENT OF JUSTICE

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April 15, 2008

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 North Market Boulevard, Suite N-219
Sacramento, CA 95834

RE: BOARD OF PHARMACY MEETING APRIL 23-24, 2008
Issuance of FDA Dockets/Requests for Information on Tracking Technologies/Identifiers
Docket Nos. FDA-2008-N-0120 & FDA-2008-N-0121
Federal Register/Vol. 73, No. 55/Thursday, March 20, 2008/Notices, pp. 14988-14992

Dear Ms. Herold:

In anticipation of the April 23-24, 2008 meeting of the Board of Pharmacy, you asked me to collect, summarize, and comment on the two Notices and Requests for Comments/Information issued by the federal Food and Drug Administration (FDA) on March 20, 2008. These "Docket" Notices were identified during the statement of Dr. Ilisa Bernstein, Director of Pharmacy Affairs for the FDA, during the March 25, 2008 Board meeting. As that statement indicated, and as you are aware, these two Notices relate to the Board's own ongoing work on electronic drug pedigree, drug product serialization, and supply chain security, as they are an example of the FDA's efforts to collect or consolidate existing information on standards for standardized numerical identifiers and other technologies necessary or important to electronic prescription drug pedigrees.

As you have also recognized, these Notices represent a further opportunity for the Board to continue its substantive engagement and partnership with the FDA on these subjects. As was reflected by Dr. Bernstein's March 25, 2008 statement, and has been otherwise made clear, most recently by Dr. Bernstein's in-person testimony in support at the hearing on SB 1307 on April 7, 2008, the FDA has been very supportive of the California model for serialization and e-pedigree. The Board and the FDA have been increasingly coordinating on pedigree recently, including with regard to standards and information the FDA is mandated to develop and collect by the Food and Drug Administration Amendments Act of 2007 (FDAAA). The FDA has recognized that its own work may capitalize on standards and information already developed and/or collected in response to the California requirements. The FDA has encouraged continuing input from the Board.

In addition to the informal input that the Board and staff will continue to provide the FDA as it goes through this process, the Board may wish to provide formal input by submitting its own responses to the Notices published by the FDA. The deadline for doing so is **May 19, 2008.** As you have requested, I will provide a framework for the Board to discuss the Notices, which might also serve as a springboard for Board discussion of possible written responses.

Background and Legal Requirements of the Notices

Copies of the two Notices, as published in the Federal Register on March 20, 2008 (pages 14988-14992), are enclosed. Docket No. FDA-2008-N-0120, titled "Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments," is first and covers pages 14988 to 14991. Docket No. FDA-2008-N-0121, titled "Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information," follows on pages 14991 to 14992. Both Notices have been issued pursuant to the language and requirements of FDAAA's Section 913, which became Section 505D of the FFDCA (the Act), and which have been codified at 21 U.S.C. § 355e. The FDA refers to these provisions by the 505D designation, rather than by the statutory codification.

As the Notices state, Section 505D includes several potentially overlapping requirements, among them that the Secretary for the Department of Health and Human Services, i.e., the FDA:

> (1) develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs;
>
> (2) in consultation with federal and state agencies, manufacturers, distributors, pharmacies and other supply chain stakeholders, prioritize and develop standards for identification, validation, authentication, and tracking and tracing of drugs;
>
> (3) by March 2010, develop a standardized numerical identifier (harmonized to the extent practicable with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing) at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug;
>
> (4) address promising technologies in this/these standards-development process(es), such as radio frequency identification (RFID) technologies, nanotechnology, encryption technologies, and other track-and-trace or authentication technologies; and
>
> (5) expand and enhance the resources and facilities of agency components of the FDA involved with regulatory and criminal enforcement of the Act to secure the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs including biological products and active pharmaceutical ingredients from domestic and foreign sources, and undertake enhanced and joint enforcement activities with other federal and state agencies, and establish regional capacities for the validation of prescription drugs and the inspection of the prescription drug supply chain.

These Notices have divided the four standards-development and information-gathering mandates into two subject areas, the first (Docket No. FDA-2008-N-0120) primarily seeking information in topic areas (2) and (3), above, with reference to topic area (1), and the second (Docket No. FDA-2008-N-0121 primarily seeking information in topic area (4), again with reference to topic (1).

Comments and Information Sought by the Notices

The clearest way to state the subject-matter division between the two Notices is that the first (Docket No. FDA-2008-N-0120) deals with all of the areas in which the FDA will set and/or adopt standards applicable to drug supply chain security, including standards for: (a) standardized numerical identifiers; (b) supply chain validation of drug products; (c) track and trace of drugs in the supply chain; and (d) supply chain authentication of drugs; as well as (e) FDA establishment of priorities among identification, validation, authentication, and tracking and tracing standards. The second (Docket No. FDA-2008-N-0121) deals more narrowly with "promising technologies" such as RFID, nanotechnology, encryption technology, or others. Though this Notice requests, as it is required to do, information on all available technologies in these categories, it is clear that its implicit focus is on RFID technology as the primary feasible technology among those listed.

Since the full text of the Notices is enclosed, I will not repeat all of the specific questions and topic areas included to encourage both broad and detailed comments and information. I will simply emphasize that should the Board elect to submit a written response to either Notice, its response(s) might comment on topics/questions identified in the Notices including whether:

- the standardized numerical identifier should contain recognizable characteristics, such as the National Drug Code (NDC) number or Global Trade Item Number (GTIN), or should instead be randomized; whether the standardized numerical identifier should be placed at the package as well as the pallet level; whether the identifier should be machine-readable, human-readable, or both; whether a consensus standard (such as those created by or under the auspices of GS1/EPCglobal) exists for such identifier and whether such standard has international acceptance and utility; and whether such identifier is in use within the U.S.;

- there exist current standards for validation, track and trace, and/or authentication of drugs within the U.S. (or global) supply chain, and what form any such standards have and/or should take in order to offer appropriate security; and whether there any implementation of such standards has taken place either domestically or globally; and

- RFID, nanotechnologies, encrypting technologies, or other technologies are viewed by the Board as "promising technologies," offer strengths for identification, validation, track and trace, or authentication that are not readily available from other technologies, and/or what limitations this technology/these technologies has/have in these areas; and whether costs of implementation and use, benefits to public health, feasibility for widespread use, and utility for e-pedigree argue in favor of adoption of this technology/these technologies.

The first two of these response categories pertain to the first Notice (Docket No. FDA-2008-N-0120), while the third pertains to the second Notice (Docket No. FDA-2008-N-0121).

Recommendation

Given the increasing cooperation between the FDA and the Board, and the explicit effort by the FDA to share in and build upon the experience and information collected by the Board, a written response from the Board to the Request(s) for Comments/Information is appropriate.

My suggestion would be that the Board discuss its possible response at the April 23, 2008 meeting, and offer guidance to staff on whether a response will be submitted, and in what form. Clearly, the Board has been exposed to a great deal of information over the last several years on the utility of various standards and technologies, including perhaps most notably those standards for data format, data carrier(s), and data transmission and sharing developed by GS1/EPCglobal, and the rapid innovations in recent months and years in RFID tag and reader technology. If the Board wished to share its impressions based on that exposure with the FDA, it may do so.

Thank you for this opportunity to present this information.

Sincerely,

JOSHUA A. ROOM
Deputy Attorney General

For EDMUND G. BROWN JR.
Attorney General

JAR:fmd

Enclosures: Federal Register/Vol. 73, No. 55/March 20, 2008/Notices, pp. 14988-14992

low power TV or TV translator operating on the same channel or first adjacent channel of its intention to initiate or change wireless operations and the likelihood of interference from the low power TV or translator station within its licensed geographic service area. The notice should describe the facilities, associated service area and operations of the wireless licensee with sufficient detail to permit an evaluation of the likelihood of interference. Upon receipt of such notice, the digital LPTV or TV translator licensee must cease operation within 120 days unless: (1) It obtains the agreement of the wireless licensee to continue operations; (2) the commencement or modification of wireless service is delayed beyond that period (in which case the period will be extended); or (3) the Commission stays the effect of the interference notification, upon request.

47 CFR 74.703(h) requires in each instance where suspension of operation is required, the licensee shall submit a full report to the FCC in Washington, DC, after operation is resumed, containing details of the nature of the interference, the source of the interfering signals, and the remedial steps taken to eliminate the interference.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–5770 Filed 3–19–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/.*

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 14, 2008.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. Select Bancorp, Inc.; to become a bank holding company by acquiring 100 percent of the voting shares of Select Bank & Trust Company, both of Greenville, North Carolina.

B. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. Cross County Bancshares, Inc., Wynne, Arkansas; to acquire additional voting shares of First Southern Bank, Batesville, Arkansas, for a total of up to 13.13 percent.

C. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. CTB Financial Corporation, Ruston, Louisiana; to acquire 100 percent of the voting shares of Community Trust Bank of Texas, Dallas, Texas, a *de novo* bank.

Board of Governors of the Federal Reserve System, March 17, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–5630 Filed 3–19–08; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Vision Health: Developing an Integrative Approach to Promotion and Protection, Request for Application (RFA) DP08–001

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Time and Date: 12:30 p.m.–3:30 p.m., April 17, 2008 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of "Vision Health: Developing an Integrative Approach to Promotion and Protection, RFA DP08–001."

Contact Person for More Information: Susan B. Stanton, D.D.S., Scientific Review Administrator, CDC, 1600 Clifton Road, NE., Mailstop D72, Atlanta, GA 30333, Telephone: (404) 639–4640.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 13, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–5628 Filed 3–19–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0120]

Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is seeking information and comments on issues related to standards for identification, validation, tracking and tracing, and authentication for prescription drug products. Particularly, we are requesting information and comments from drug manufacturers, distributors, pharmacies, other supply chain stakeholders, foreign regulators, standards organizations, and other Federal agencies and interested parties. This request is related to FDA's implementation of the Food and Drug

Administration Amendments Act of 2007 (FDAAA).

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled "Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information."

DATES: Submit written or electronic comments by May 19, 2008.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.Regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Ilisa Bernstein, Office of Policy, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, e-mail: *ilisa.bernstein@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, FDAAA (Public Law 3580) was signed into law. Section 913 of this legislation created section 505D of the Federal Food, Drug, and Cosmetic Act (the act), which requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. Section 913 directs the Secretary to consult with specific entities to prioritize and develop standards for identification, validation, authentication and tracking and tracing of prescription drugs. Section 913 of this legislation also directs the Secretary to develop a standardized numerical identifier which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier, no later than 30 months after the date of the enactment of FDAAA. This standardized numerical identifier is to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing) at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.

FDA has been engaged in an intense effort to address counterfeit drugs for several years. In 2004, FDA's Counterfeit Drug Task Force released a report (Task Force Report) outlining a framework for public and private sector actions that could further protect Americans from counterfeit drugs, including implementation of new track and trace technologies to meet and surpass goals of the Prescription Drug Marketing Act, the Federal pedigree law.

In 2006, FDA issued an update report after conducting a fact-finding effort to determine how much progress had been made toward e-pedigree and electronic track and trace. FDA found that although significant progress was made to set the stage for widespread use of e-pedigree in 2007, this goal likely would not be met. Currently, there is no widespread use of e-pedigree.

Currently, e-pedigree is not in widespread use across the supply chain.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled "Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information." This related document seeks information from technology vendors and others regarding available and emerging technologies for identification, validation, track and trace, and authentication of prescription drugs, as set forth in 505D(b)(3) of the act.

With this document, as a first step in developing standards under section 505D(b) of the act, we are seeking information from drug manufacturers, distributors, pharmacies, other supply chain stakeholders, foreign regulators, standards organizations, other Federal agencies, and other interested parties related to identification, validation, authentication, and tracking and tracing of prescription drugs. Consistent with the act, it is FDA's preference that such standards be the result of existing private and public sector collaborative standards processes. FDA intends to use the response to these comments to determine the state of standards development in these areas and determine how aggressively it may move forward. Recognizing the importance of uniform standards as well as the need to allow for updating over time, FDA would consider adopting such standards through a guidance process as quickly as possible.

II. Request for Comments

Please comment on the following questions regarding the development of standards related to section 505D of the act.

A. Standard Numerical Identifier

1. Characteristics

a. Should the standardized numerical identifier contain recognizable characteristics (e.g., National Drug Code number) or be random codes?

b. Should there be a common header for item/product segregation based on product type: biologic, solid oral dosage form, etc.? If so, please elaborate.

c. How can parties in the supply chain ensure that the numbers are unique and are not duplicated?

d. How much value would there be in having the numerical identifier in more than one place for the product (e.g., package and pallet level)?

e. Should the numerical identifier be machine readable, human readable, or both?

f. Should the numerical identifier include the lot number and/or batch number?

2. Standards

a. Do standards currently exist for a standardized numerical identifier of prescription drugs?

1. If so, please describe and comment on their application and use.

2. To what extent do these standards reflect stakeholder consensus?

3. Comment on whether any of these standards should be the standard adopted by FDA.

4. If yes, why? Compare this standard with other standards that exist.

5. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

6. Has this standard been adopted by other countries?

b. Are standards in development or planned for standardized numerical identifiers of prescription drugs in the supply chain? If so, who is developing these standards and what is the timeline for completion?

c. What are the elements, provisions, and particular considerations that should be included in a standardized numerical identifier of prescription drugs? Please be specific in your response and include examples, where possible.

d. Please comment on implementation of standardized numerical identifiers of prescription drugs in the U.S. supply chain.

e. Please comment on any technical or information technology concerns related to a standardized numerical identifier.

f. Comment on any "lessons learned" from foreign experience with standardized numerical identifiers.

3. Economic Impact

a. What are the usual practices and associated costs that now exist for applying bar codes and other technologies for standardized numerical identifiers on packages and pallets?

b. What are the associated costs for the application, use, and maintenance of standardized numerical identifiers?

c. What are the associated costs or processes for updating the standards as needed?

d. What are the benefits of using standardized numerical identifiers?

4. Harmonization With Other Countries

a. What standards or unique identification systems do other countries have in place, currently under development, or planned for the future? If they are under development, please include a timeline for completion.

b. Comment on any "lessons learned" from foreign experience with standardized numerical identifiers.

B. Standards for Validation

1. Do standards currently exist for validation of prescription drugs?

a. If so, please describe and comment on their application and use.

b. To what extent do these standards reflect stakeholder consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

2. Are standards in development or planned for validation of prescription drugs in the supply chain?

If so, who is developing these standards and what is the timeline for completion?

3. What are the elements, provisions, and particular considerations that should be included in a validation standard for prescription drugs? Please be specific in your response and include examples, where possible.

4. Please comment on implementation of validation of prescription drugs in the U.S. supply chain.

5. Please comment on any technical or information technology concerns related to validation.

6. Comment on any "lessons learned" from foreign experience with validation.

C. Standards for Track and Trace

1. Do standards currently exist for track and trace of products in the supply chain, generally?

a. If so, please describe and comment on their application and use.

b. To what extent do these standards reflect stakeholder consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

g. If standards are under development or planned for the future, please include a timeline for completion.

2. Do standards currently exist for track and trace of prescription drug products in the supply chain?

a. If so, please describe and comment on their application and use.

b. To what extent do these standards reflect stakeholders consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

3. Are standards in development for track and trace of prescription drugs in the supply chain?

If so, who is developing these standards and what is the timeline for completion?

4. What are the elements, provisions, and particular considerations that should be included in a track and trace standard for prescription drugs? Please be specific in your response and include examples, where possible.

5. Please comment on implementation of track and trace for prescription drugs in the U.S. supply chain, including, but not limited to, feasibility, costs, timeline, interoperability, information technology, and data storage.

6. Discuss how the data generated from track and trace should be held, where it should be held, concerns related to data security, and means for access to ensure interoperability for data sharing. What elements should be included in such a standard for data exchange, storage, and interoperability?

7. Comment on any "lessons learned" from foreign experience with track and trace.

D. Standards for Authentication

1. Do standards currently exist for authentication of products in the supply chain, generally?

a. If so, please describe and comment on the application and use.

b. To what extent do these standards reflect stakeholders consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

2. Do standards currently exist for authentication of prescription drug products in the supply chain?

a. If so, please describe and comment on the application and use.

b. To what extent do these standards reflect stakeholders consensus?

c. Comment on whether any of these standards should be the numerical identifier standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

3. Are standards in development for authentication of prescription drugs in the supply chain?

If so, who is developing these standards and what is the timeline for completion?

4. What are the elements, provisions, and particular considerations that should be included in an authentication standard for prescription drugs? Please be as specific as possible and include examples, where possible.

5. Please comment on implementation of authentication for prescription drugs in the U.S. supply chain, including, but not limited to, feasibility, costs, timeline, interoperability, information technology, and data storage.

6. Comment on any "lessons learned" from foreign experience with authentication.

E. Prioritization

Please comment on the priority for development and implementation of identification, validation, authentication, and tracking and tracing standards.

1. Should certain standards be developed and implemented before others?

2. Should certain standards be developed and implemented concurrently?

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments and information. Submit a single copy of electronic comments and information or two paper copies of any mailed comments and information, except that individuals may submit one paper copy. Comments and information are to be identified with the name of the technology and the docket number

found in brackets in the heading of this document. A copy of this notice and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: March 13, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–5597 Filed 3–19–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0121]

Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments and information regarding technologies used for the identification, validation, tracking and tracing, and authentication of prescription drugs. This request is related to FDA's implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA).

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled "Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments."

DATES: Submit written or electronic comments and information by May 19, 2008.

ADDRESSES: Submit written comments and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments and information to *http://www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ilisa Bernstein, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–03, Rockville, MD 20857, phone: 301–827–3360, FAX 301–594–6777, e-mail: *ilisa.bernstein@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, FDAAA (Public Law 3580) was signed into law. Section 913 of this legislation requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. Specifically, section 913 created section 505D(b) of the Federal Food, Drug, and Cosmetic Act (the act), which directs the development of standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. Section 505D(b)(3) states that the standards developed under 505D "shall address promising technologies, which may include—(A) radio-frequency identification; (B) nanotechnology; (C) encryption technologies; and (D) other track and trace or authentication technologies."

FDA has previously identified counterfeit drugs as a threat to the safety of the public and the pharmaceutical supply chain.

1. In 2004, FDA's Counterfeit Drug Task Force issued a report (Task Force Report) on the threat of counterfeit medications and measures that can be taken by private and public stakeholders to make the U.S. drug supply chain more safe and secure. The 2004 Task Force Report stated, among other things, that:

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- Radio Frequency Identification (RFID) is a promising technology as a means to achieve e-pedigree; and
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007.

2. In 2006, the Task Force issued an update report which stated that the goal of widespread use of e-pedigree and track and trace technologies by 2007 would probably not be met. The voluntary approach taken did not provide enough incentives for the adoption and implementation of the technologies and e-pedigree.

As part of the efforts listed above, we received information about various technologies for the identification, track and trace, and authentication of prescription drugs, and we met with companies to learn more about these technologies. We are aware that significant progress has been made and new technologies are emerging for the identification, track and trace, and authentication of prescription drugs. In order to address the "promising technologies" related to standards development, as described in section 505D(b)(3) of the act, we are seeking information from technology vendors and others. Rather than meet individually with companies, for efficiency and to further our understanding and knowledge, we are requesting that information be submitted to the docket number listed above.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled "Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments." Under section 505D(b)(1) and (b)(2) of the act, this related document seeks information from drug manufacturers, distributors, pharmacies, other supply chain stakeholders, foreign regulators, standards organizations, and other Federal agencies and interested parties on issues related to standards for identification, validation, tracking and tracing, and authentication for prescription drug products.

We are particularly interested in the following information regarding available and emerging technologies for identification, validation, track and trace, and authentication of prescription drugs:

1. What are the RFID technologies, encrypting technologies, and nanotechnologies that are relevant? What are other relevant technologies?

2. Please provide information related to:

- Strengths for identification, validation, track and trace, or authentication;
- Limitations for identification, validation, track and trace, or authentication;
- Costs of implementation and use;
- Benefits to the public health;
- Feasibility for widespread use;
- Utility for e-pedigree.

3. Is the technology interoperable with other technologies? If so, describe.

4. What standards are necessary for supply chain use of the specific technology? What is the status of development of such standards?

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments and information. Submit a single copy of electronic comments and information or two paper copies of any mailed comments and information, except that individuals may submit one paper copy. Comments and information are to be identified with the name of the technology and the docket number found in brackets in the heading of this document. A copy of this notice and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: March 13, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–5599 Filed 3–19–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Clinical Grant Applications.

Date: March 26, 2008.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Houmam H. Araj, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, NIH, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892–9602, 301–451–2020, *haraj@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Eye Institute Special Emphasis Panel, Secondary Data Analysis Grant Applications.

Date: March 28, 2008.

Time: 3 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Houmam H. Araj, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, NIH, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892–9602, 301–451–2020, *haraj@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Epidemiology Grant Applications.

Date: April 1, 2008.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health/NEI, 5635 Fishers Lane, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Anne E. Schaffner, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892–9300, (301) 451–2020. *aes@nei.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Genetics and Genomics Applications.

Date: April 10, 2008.

Time: 12:30 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health/NEI, 5635 Fishers Lane, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Anne E. Schaffner, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892–9300, (301) 451–2020, *aes@nei.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: March 13, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–5568 Filed 3–19–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments Are Invited On: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The Coordinating Center to Support State Incentive Grants to Build Capacity for Alternatives to Restraint and Seclusion (OMB No. 0930–0271) Revision.

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services has funded a Data Collection and Analysis for the Alternatives to Restraint and Seclusion Grant Program. This contract is an evaluation of SAMHSA's State Incentive Grants to Build Capacity for Alternatives to Restraint and Seclusion. These grants are designed to promote the implementation and evaluation of best practice approaches to reducing the use of restraint and seclusion in mental health facilities. Grantees consist of 8 sites (state mental health agencies), all of which will be implementing