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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Reference: Docket No. 2005N-0510
Anti-Counterfeit Drug Initiative

Attention: Co-Chairs, FDA Counterfeit Drug Task Force -2006

Margaret Glavin
Associate Commissioner for Regulatory Affairs
Office of Regulatory Affairs

Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning
Office of the Commissioner

Dear Ms. Glavin and Dr. Lutter:

On February 9, 2006, I spoke at the FDA workshop on the panel addressing the "PDMA in 2007 and Beyond". One of my suggestions to the task force addressed the need for a coordinated, centralized effort that brings together the intelligence resources necessary to detect, prevent and mitigate pharmaceutical crimes.

I would like to follow-up those brief remarks with this more detailed submission to the FDA docket. I have attached a White Paper on *An Intelligence Strategy to Enhance the Security and Integrity of our Drug Supply Chain*. The paper was written with the support of Science Applications International Corporations (SAIC), a provider of analytical intelligence systems and services to the federal military, law enforcement and regulatory communities. SAIC owns the intellectual property rights to the *Pathfinder* analytical tool suite utilized by FDA's Office of Criminal Investigations (OCI), and they would be well-positioned to support this effort.

The White Paper provides a high-level overview of the intelligence approach I would suggest. I would welcome the opportunity to meet with the task force, with a representative from SAIC, to provide more detail and to answer any questions you may have.

Thank you for you ongoing efforts in this very important area.

Stephen J. Haynes
President
Integrity Resource Group, Inc.

AN INTELLIGENCE STRATEGY TO ENHANCE THE SECURITY AND INTEGRITY OF OUR DRUG SUPPLY CHAIN

Illegal drug diversion, fraudulent Internet drug sales, drug counterfeiting, and malicious tampering pose significant challenges to those charged with protecting the safety and health of our citizens. The complex nature of the criminal acts and the often international scope of the illegal activities pose unique security problems, and significant hurdles to the investigative response.

The risks these pharmaceutical crimes present are real. They require a proactive, comprehensive security capability – a capability that optimizes the ability to prevent, respond, and mitigate.

How can we enhance this capability, and in turn improve the safety, security and integrity of our drug supply chain? The answer rests in our ability to strengthen our health "intelligence" assets. We must improve our ability to collect, extract, analyze and report information specific to these pharmaceutical crimes; and we must provide security and law enforcement professionals with the tools they need to help ensure public safety.

GETTING OUR ARMS AROUND THE PROBLEM

Crimes impacting on the integrity of our drug supply are not new. In 1985 a Congressional subcommittee reported that because of illegal drug diversion, American citizens frequently purchased prescription drugs with little assurance that what they were getting was safe and effective. The report disclosed that drugs were mislabeled, subpotent, adulterated, expired, and sometimes counterfeit. It highlighted problems with drugs being illegally reimported into the United States, with a systemic problem of wide scale domestic wholesale diversion of prescription drugs, and with problems posed by the diversion of drug samples.

To what extent do these problems still exist today?

In many ways, the extent of the problems are not well defined – a further indication of the need to strengthen and focus our intelligence efforts. What we do know, however, is:

- the Internet provides a largely anonymous, often complex maze, involving the illegal sale of potentially dangerous medicines.

- there is a known proliferation of illegal imports, with an ongoing Congressional debate that could loosen existing import requirements and increase supply chain vulnerabilities.

- that the FDA, in its 2004 Counterfeit drug task force report, noted the agency *"has seen growing evidence of efforts by increasingly well organized counterfeiters backed by increasingly sophisticated technologies and criminal operations to profit from drug counterfeiting at the expense of American patients."*

- sophisticated criminal enterprises involving gray market diversion and counterfeiting provide the mechanism to obtain, conceal and launder illegal profits – profits available to further organized crime and terrorist activity.

- in the aftermath of the 9/11 tragedy, there is an increased awareness of the potential – and impact – of a malicious product tampering, terrorist event; an ever-increasing focus on the need to strengthen supply chain security and import controls; and ongoing efforts to enhance intelligence gathering, analysis and sharing.

We will never get our arms around the extent of these pharmaceutical crimes – and will never be in a position to adequately respond – without a significantly strengthened intelligence capability. We need to improve our ability to gather information and data unique to these crimes; we need a focal point for collection, analysis and dissemination of information; we need the necessary technical and analytical tools; and we need to build an analytical expertise in this critical health intelligence area.

THE CHALLENGES

Perhaps the biggest challenge in moving forward is to recognize the need to improve our intelligence capabilities, and to start the "solution" process. The pharmaceutical supply chain is complex, as are the vulnerabilities that must be addressed.

> Is the online purchase of pain medicine that arrives in a small unmarked baggie a relatively innocent transaction, or the part of a larger criminal scheme?
>
> Is the diversion of domestic wholesale product a civil fraud against the manufacturer, or the means to introduce counterfeit and dangerous medicines to an unsuspecting public?
>
> Is the small secondary wholesaler an authorized distributor, or a front to move illegal product?
>
> Is the foreign provider of APIs or excipients an authorized source, or a means to introduce subpotent, tainted, or unsafe product?
>
> Is the criminal a "con-artist", or part of a sophisticated criminal or terrorist activity?

The challenges encompass many of the recognized and long-standing issues familiar to law enforcement and security professionals: How to best capture information and data from diverse, complex sources; and how to maximize the ability to analyze, share, and provide a timely security or investigative response.

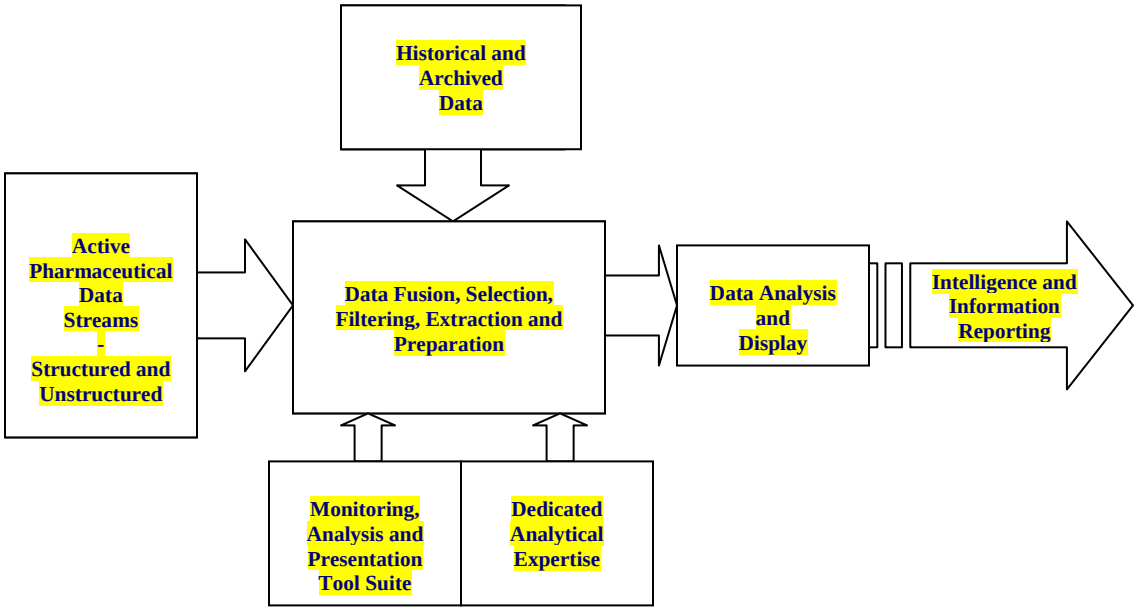
These challenges can be magnified within the pharmaceutical industry – an industry with realistic concerns about company and product sensitive data and business competition. The solutions must recognize these legitimate concerns, and provide the necessary controls and assurances.

THE SOLUTION AND ITS COMPONENTS:
A Pharmaceutical Crimes Intelligence Center

Today there is no coordinated, centralized effort that brings together the intelligence resources necessary to detect, prevent and mitigate pharmaceutical crimes.

The problems aren't being ignored. There are many valuable efforts by both government agencies and the pharmaceutical industry to respond to the threats and vulnerabilities within the system – and to decrease the related risks to the American consumer. Unfortunately, those efforts don't translate to a conclusion that we are where we need to be.

The solution is to create a Pharmaceutical Crimes Intelligence Center with traditional intelligence analysis capabilities – capabilities that have been successfully used in other security and enforcement arenas.



THE BASIC ANALYTICAL PROCESS

Information and Data Categories

Much of the information we need is available – the solution is to obtain and merge the sometimes disparate data under a focused intelligence umbrella: an intelligence facility with dedicated retrieval, analysis and modeling tools joined with specific analytical expertise.

In the pharmaceutical arena it means capturing open and closed source information, structured and unstructured data, and both historical and current information flows. It means providing options for storing and organizing data, and offering models to provide visual representations of complex problems.

It means building databases – or connecting information silos - that are specific to government and industry needs, and that address the myriad of crimes and vulnerabilities.

It means capturing information specific to the production process, foreign and domestic:

- Manufacturers of Active Pharmaceutical Ingredients
- Manufacturers of Pharmaceutical Excipients
- Finished Product Identifiers and Imagery
- Authentic Packaging and Imagery

It means identifying legitimate distribution, shipping and logistics firms, foreign and domestic:

- Authorized Primary and Secondary Wholesalers
- Licensed Compounders and Re-Packaging Operations
- Authorized Import Firms and their Business Partners

It means capturing available government source data:

- Criminal investigative
- Import Specific
- Science and Health Safety
- Homeland Security

It means tapping global pharmaceutical efforts:

- Interpol, WHO, EU, and others

It means capturing country specific intelligence and resources:

- Court records
- Regulatory Requirements and Actions
- Suspect/Defendant Data
- Open Source Information

It means the ongoing monitoring of Internet/Web data:

- Site Specific, Auctions, Message Boards, Spam Advertisers, News Groups, Chat Rooms

It means utilizing company and industry specific information:

- Sales, Logistics, Investigative Reports, 3rd Party Vendor Support

It means bringing the above together, identifying knowledge gaps and information needs, and implementing a process for ongoing intelligence enhancement.

Finally, it means combining these information sources with the necessary analytical tools and expertise.

Analytical Tools and Expertise

The Pharmaceutical Crimes Intelligence Center concept brings together critical analytical tools, and integrates technical capabilities to support the analytical process. It serves as the focal point for multi-domain data mining and analysis solutions, and leverages internal and external expertise necessary to address specific problems.

The tool solutions will integrate existing intelligence applications and technologies as the framework for a flexible, fusion center approach addressing pharmaceutical crimes and intelligence gathering. Those tools, combined with the ability to build and continually improve upon analytical expertise, offer the best opportunity for document exploitation, data mining, information sharing, and analytical intelligence for interested organizations.

THE BENEFITS

The benefits to this intelligence center approach are numerous. They include:

- Establishing a pharmaceutical crimes focal point - with the specific mission of protecting public health and meeting the needs of security and law enforcement professionals.

- Providing the ability to create multiple and diverse databases; and to integrate and share information across a broad spectrum of pharmaceutical concerns.

- The ongoing means to build and blend data – continually strengthening intelligence benefits.

- The ability to refine techniques and total system solutions based on client needs.

- The opportunity to integrate a variety of analytical, geo-spatial, and link-charting applications.

- Utilizing subject matter experts – pharmaceutical, technical and analytical – toward mutual objectives.

- Enhancing cost-effectiveness by eliminating duplicate efforts and sharing costs.

SAIC – A PART OF THE SOLUTION

Science Applications International Corporation is a provider of analytical intelligence systems and services to the federal military, law enforcement and regulatory communities. These federal law and regulatory enforcement agencies have applied SAIC's Pathfinder resources to document exploitation, data sharing, investigative and information management, analytical intelligence, litigation support, computer forensics, visualization projects, and modeling efforts. Additionally, Pathfinder capabilities have been used to address both structured and unstructured open source data acquisition projects that directly impact multiple program requirements.

Pathfinder began in 1985 as an effort to help intelligence analysts track threats unique to the Cold War. Project Pathfinder has continued to evolve since then and remains a centerpiece for developmental and operational intelligence support within the Department of Defense military intelligence community.

The controlling "program office" for Project Pathfinder is the Advanced Intelligence Program Office at the United States Army's National Ground Intelligence Center. The program office has been helpful in moving this application (Pathfinder Data Mining and Visualization Tool Suite), and associated methodologies, to interested federal law and regulatory enforcement agencies. Presently, there are over 40 government organizations utilizing Pathfinder, including DHS, DoD and FDA's Office of Criminal Investigations.

Pathfinder, integrated with other analytical tools and resources, would provide a valuable component in the fight against pharmaceutical crimes. The ***Pharmaceutical Crimes Intelligence Center*** would serve as the fusion center in this fight, and as a valuable government and industry asset in the ongoing efforts to fight drug counterfeiting and diversion.

SAIC, with its documented expertise and capabilities, is well-positioned to support these critical efforts to improve the security and integrity of our nation's drug supply.