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# An Emerging Role of Regulatory Affairs in the Drug Development Process

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**ABSTRACT:**

In the pharmaceutical industry, developing a novel chemical which have a significant negative influence possess to ensure the quality, safety, and effectiveness to maintaining all records and papers as well as keeping products in conformity are entirely the regulatory affairs professional's responsibilities. Although the road to drug registration and marketing approval is paved with good intentions, it can be challenging, drug development and commercialization are highly regulated industries evolving the CFR. Code of Federal Regulations (CFR) is the codification of the general and permanent rules and regulations (sometimes called administrative law) published in the Federal Register by the executive departments and agencies of the federal government of the United States. It is divided into 50 titles. Each title is further divided into chapters, subchapters, parts, and sections. Many in the Regulatory Affairs Profession believe the New Approach to regulation will eventually be adopted for all healthcare products as it represents the best model for delivering new healthcare advances to market in a reasonable time with acceptable safety. Regulatory Affairs department is constantly evolving and growing and is the one which is least impacted during the Acquisition and Merger, and also during recession.

## I. INTRODUCTION

The global pharmaceutical business and drug regulatory authorities are connected viatheregulatoryaffairs(RA)profession.Priortobeing marketed,druggoodsmustfirstberegistered in the appropriate countries. The organizational structure of pharmaceutical businessesincludesthedrugregulatoryaffairsdepartment,whichissignificant.Thepharmaceuticalindustry is well-organized, systematic, and adheres to worldwide regulatory requirements for theproductionofmedicalequipment,traditionalherbal items,cosmetics,andchemicalandbiological medications for human and veterinary consumption(1).Every part of the process,from formulating regulatory strategies after the discovery of a new chemical entity to organizingpostmarketingactivities,benefitsfromthee xpertiseofthedrugregulatoryaffairsprofessional.

(2) In the pharmaceutical industry, developing a novel chemical can cost millions of dollars orrupees,andanymistakeshaveasignificantnegativei nfluenceonacompany'sreputation.Medicine laws are necessary to ensure the quality, safety, and effectiveness of medicationsbecause they are so important to human health. Maintaining all records and papers as well askeeping products in conformity are entirely the regulatory affairs professional's responsibilities.Any oversight in the regulatory, quality control, or safety-related processes could result in therecalloftheproductandtheconsequentlossofmillio nsofdollars.Allfacetsofdrugdevelopment, from research to commercialization, are very regulated. Clinical trials are requiredfor every drug before it can be approved for sale in order to guarantee its quality, safety, andefficacy.(3)

**OBJECTIVE:**

Examine the administrative issues calling and the requirement for drug guideline Give an outlineof a few Regulatory Authorities Identify key improvement achievements that initiatate FDAcollaboration Discuss the various jobs and capability inside Regulatory Affairs Highlights theworthof drug specialists in Regulatory Affairs jobs.

- Toresearchapositioninregulatoryaffairs forthe pharmacyindustry
- The provision of fundamentals in the area of regulatory affairs in accordance withindustryrequirements

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- Keeping up with the region's constantly evolving legal landscape application in thedifferentstagesofgrowth,currentunderstanding ofinternationalrules andregulations
- theoreticalexpertiseincreatingandsubmittingthe documentsthatthehealthcarebusinessandregulatoryauthoritiesrequireforthe registrationofprofessionals

**WHYISREGULATORYAFFAIRSNEEDED?**

Although the road to drug registration and marketing approval is paved with good intentions, itcan be challenging, drug development and commercialization are highly regulated industries.Thingsarecontinually evolving.

**PARAMETEROFREGULATORYAFFAIRS:**

- DevelopmentDesignPlanCo-ordinationWriting/reviewingsupervising
- Drugregulation
- NationalLaws(e.g.,UK- MedicinesAct,US-CFR)
- RegionalLaws(ECdirectives)
- ConstructionAssembling&SubmissionManagementTestingWherearetheweaknesses
- NationalandRegional Guidelines
- InternationalGuidelines(ICH)

**SCOPEOFREGULATORYAFFAIRSPROFESSIONINININDUSTRIES:**

- Professionalsinregulatoryaffairsworkinacademia,governmentregulatoryagencies, and industry. Themany regulatoryexpertswork in variousfields.

**REGULATORYAUTHORITY**

Drug administrative specialists and drug makers share a shared objective: to advance the generalwellbeingbyguaranteeingthatprotected,compelling,appropriatelynameddrugitems,fabricated toexclusiverequirementsof valuearecreated, tried,assessed, andendorsedforshowcasingin the basemeasureof time. (4)

**REGAULATORYBODIESIN THEWORLD (2):**

| COUNTRY | REGULATORYAUTHORITY |
|---|---|
| India | CentralDrugsStandardControlOrganization DrugcontrollergeneralofIndia(DCGI) |
| US | FoodandDrugAdministration(USFDA) |
| UK | Medicines and Health care products regulatoryAgency(MHRA) |
| Australia | TherapeuticGoodsAdministration(TGA) |
| Japan | JapaneseMinistryofHealth,Labourand Welfare(MHLW) |
| Canada | HealthCanada |
| Brazil | Agency National degradation Vigilancia Sanitaria(ANVISA) |
| SouthAfrica | MedicinesControlCouncil(MCC) |
| Europe | European Directorate for Qualityof Medicines (EDQM)European Medicines Evaluation agencies (EMEA) |

**DISTRIBUTIONOFREGULATORY FUNCTIONS ALONGTHE DRUFGPRODUCTLIFE CYCLE:**

**CLINICALTRAILS:**

- Applicationsonlineintheclinicaltrialsregistry India
- Approvalofapplications
- Goodclinicalpractice
- Inspections
- Registrationsofethicscommittee
- Seriousadverseevents(SAE

**AuthorityResponsible:**CDSCO(appointedbytheMOHFW,CentralGovernment.)hasthesoleresponsibility – relies on expert committees.

**NEWDRUGAPPROVALS:**

- 12subjectexpert committees(SECs)fordeliberationonnewdrugapplicationforgrantofmarketinglicense
- Importofnewdrugs (Registrationofforeignmanufactureofforeignma

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nufacturersandgrantof licenseto import)
**AuthorityResponsible:**CDSCOhasthe soleresponsibility

**MANUFACTURING:**
- ApplicationforLicencetomanufacture(Generics andthosewithmarketing license)
- InspectionofGoodManufacturingPractices(WHOGMP/ScheduleM)
- GrantofLicencetoManufacture
- CollectionofSamples,testingandprosecutionfor Noncompliance

**Authority Responsible:**SDRA (appointed by the Department of Health, State Government) hasprimaryresponsibility
Exceptions (CDSCO competence) - CDSCO acts as SDRA in Union Territories (e.g. Delhi) -WHO-GMP Inspections - High Risk Products (IV Fluids, Large volume parenteral, Vaccine andSera, Blood and Blood Products, r-DNA products (CDSCO may include new products in this listvianotification)

**DISTRIBUTIONANDSALE:**
- ApplicationforLicenceto distributeandsell
- InspectionofGoodDistributionPractices(GDP) andsalepremises
- GrantofLicenceto distributeandsell
- ProsecutionforNon-Compliance

**AuthorityResponsible:**SDRA hasthesole responsibility

**POSTMARKETINGSURVEILLANCE:**
- Periodic Safety Update Reports (PSURs) required to be submitted (Schedule Y of theDrugsand Cosmetics Rules)fornewdrugs granted marketing license
- BanningofDrugs consideredharmful orsubtherapeuticunderSec. 26Aof theDCA
- Pharmacovigilance Programme of India (PvPI) is the national coordinating center forcollectingAdverseDrugReactionReportsfromAdverseDrugMonitoringCentre(AMCs)

**Authority Responsible:**CDSCO has sole responsibility for PSURs and Indian PharmacopoeiaCommission(IPC) is inchargeofcoordinating AdverseDrug Reports (ADRs). (13)

**NEWDRUGADMINISTRATION:**

Model-based drug improvement supported by Lewis Sheiner, in whichpharmacostatistical models of medication viability and wellbeingare created from preclinicaland accessible clinical information, offers a quantitative way to deal with further developingmedicationadvancementand advancementnavigation. (5)

**NEWDRUGAPPLICATION PROCESS:**

Theprocessstartswithpreclinicaltesting.For drugsthatappearsafe,aninvestigationalnewdrug applicationisfiledwiththeFDA.Ifapproved,clinicaltrialsbeginwith;
- **Phase1**studiesthatfocusonsafetyandpharmacology
- **PhaseII**studiesexaminetheeffectiveness ofthecompound.
- **Phase III**before submitting a new drug application (NDA) to the FDA, is the last step.AnNDAincludesall thedata gathered throughoutall testingrounds.
- **Phase IV**Studies are carried out following the approval of a product (post marketingstudies).Theapprovalprocesshasbeen simplifiedasaresultofrecentlegislativechanges. (6)

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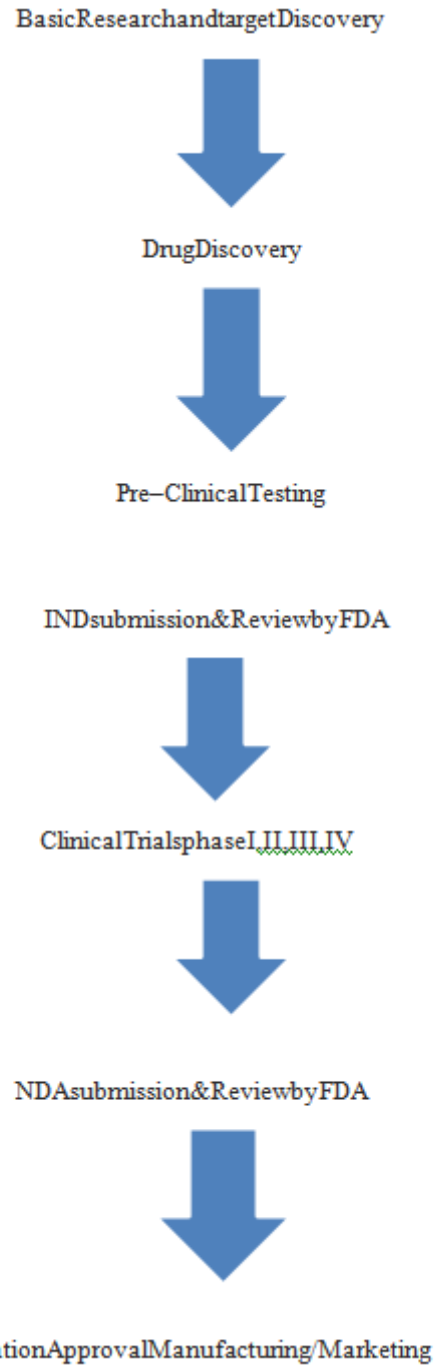
**Drugdevelopment/Approval:**




**ABBREVIATEDNEWDRUGAPPLICATION:**

Abbreviated New Drug Application (ANDA) must have information to showthattheproposedgenericproductandtheinnovatorproductareboth pharmaceuticallyequivalentandbioequivalent, and therefore, therapeutically equivalent

**INVESTIGATIONALNEWDRUG:**

An Investigational New Drug (IND) treatment programallows patients accessto a drug that has shown activity against a serious or life-threatening disease prior to full Foodand Drug Administration (FDA) review and approval. This treatment IND program, in whichpatients with locally advanced or metastatic pancreatic

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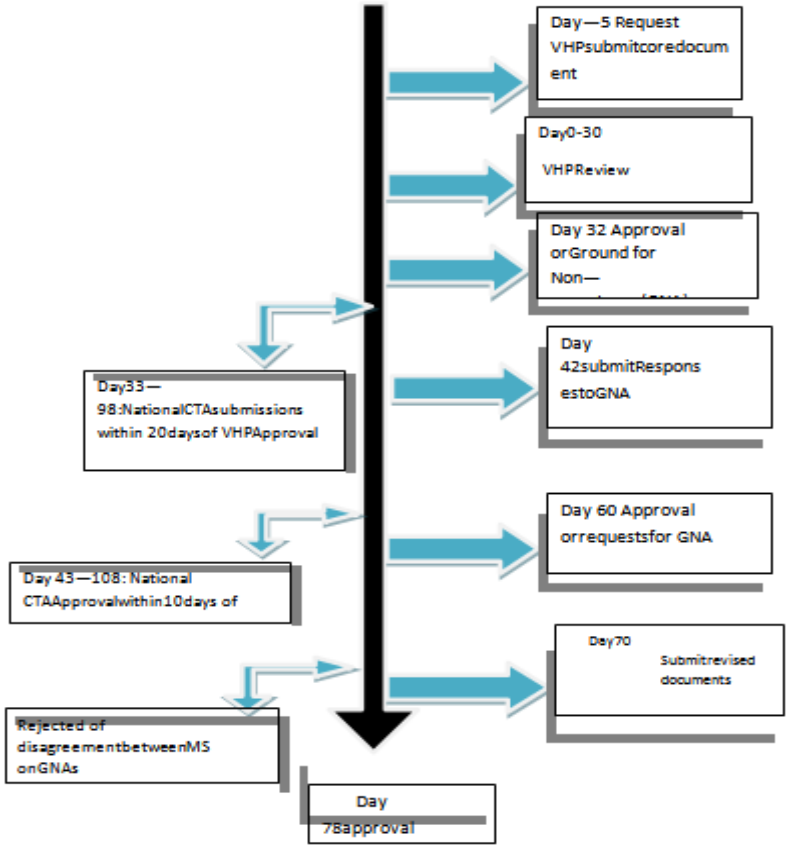
carcinoma were treated with gemcitabine,beganin 1995

The Federal Food, Drug and Cosmetic Act prohibits the shipment of a new druginto interstate commerce unless there exists for that drug an approved NDA or an effective INDapplication. Unlike certain European countries, such as Germany and the United Kingdom, theexistence of anIND is requiredregardless of the proposed phase of clinical trial. Thus, evenphase 1trialstobe conducted inthe United Statesonvolunteer subjectsrequire the priorsubmission of an IND before that trial may be undertaken. An Investigational New Drug (IND)treatment program allows patients access to a drug that has shown activity against a serious orlife- threatening disease prior to full Food and Drug Administration (FDA) review and approval.This treatment IND program, in which patients with locally advanced or metastatic pancreaticcarcinoma weretreatedwith gemcitabine, (7)

**MEDICALDEVICE(CTD):**

TheCommonTechnicalDocument(CTD)isa bunchofparticularforapplication dossier forth enlistment of Prescriptions and ready to be utilized across Europe,Japan and the Unified States. It is a universally concurred design for the arrangement of uses inregards to new drugs planned to be submitted to local experts in the nations. It was created by theEuropean Medicines Agency (EMA, Europe), the Food and drug administration (FDA, U.S.) andthe Service ofWellbeing,WorkandGovernmentassistance (Japan). The CTDiskeptupwithbytheWorldwideMeetingonHarmonizationofSpecializedPrerequisitesforEnlistmentof DrugsforHuman Use(ICH).(13)




**CODEOFFEDERALREGULATIONS(CFR):**

Code of Federal Regulations (CFR) is the codification of the general and permanent rulesand regulations (sometimes called administrative law) published in the Federal Register by theexecutive departments and agencies of the federal government of the United States. The CFR isdivided into 50 titles that represent broad areas subject to federal regulations. Each title is furtherdividedintochapters,subchapters,parts,andsections.TheonlineCFRisajointprojectauthorized by the publisher, the National Archives and Records

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Administration's (NARA) Officeof the Federal Register (OFR), and the Government Publishing Office (GPO) to provide thepublicwith enhancedaccess to Government information.
"The Code of Federal Regulations (CFR) annual edition is the codification of the generaland permanent rules published in the Federal Register by the departments and agencies of theFederalGovernment."
Itisdividedintothree chapters:

VOLUME I - Food and Drug Administration
VOLUME II - Office of National Drug Control Policy
VOLUMEIII-DrugEnforcementAdministration

**PARTS:**
PART 1-General Provisions
PART2-GrantsandAgreementsPART3-ThePresident
PART4-Accounts
PART 5-Administrative Personnel
PART6-DomesticSecurity
PART7-Agriculture
PART8-AliensandNationality
PART9-AnimalsandAnimalProducts
PART10-Energy
PART 11-Federal Elections
PART12-BanksandBanking
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PART14-AeronauticsandSpace
PART15-CommerceandForeignTrade
PART16-CommercialPractices
PART17-CommodityandSecuritiesExchanges
PART18-ConservationofPowerandWaterResources
PART19-Customs Duties
PART20-Employees'Benefits
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PART29-Labor
PART30-MineralResources
PART31-MoneyandFinance:Treasury
PART32-National Defense
PART33-NavigationandNavigableWaters
PART34-Education
PART35-PanamaCanal[Reserve
PART 36-Parks, Forests, and Public PropertyPART 37- Patents, Trademarks, and CopyrightsPART38-Pensions,Bonuses,andVeterans'ReliefPART39-Postal Service
PART40-ProtectionofEnvironment
PART 41- Public Contracts and Property ManagementPART42-PublicHealth
PART43-PublicLands:Interior
PART44-EmergencyManagementandassistancePART45-PublicWelfare
PART46-Shipping
PART47-Telecommunication
PART48-FederalAcquisitionRegulationsSystem.PART49-Transportation
PART50-WildlifeandFisheries (8)

**VOLUME I: THE FOOD AND DRUG ADMINISTRATIONINTRODUCTION:**

The Food and Drug Administration (FDA) is responsible for the regulation of the pharmaceuticalindustry in the interest of protecting public health. The aim of this review was to outline the evolution andcurrent role of the FDA in the development and approval of new drugs. Additionally, we describe currentassessments of proarrhythmic risk to illustrate recent FDA initiatives intended to harness informationtechnology to modernize the regulatory process. In order to identify the literature required to produce thisreview, search tools such as PubMed and Google Scholar were used to locate relevant web pages andarticles.

The job of the FDA is not only to ensure that high standards for drug efficacy and safety areapplied to products available to American consumers and patients but also to balance the lengthy, costlyprocess of maintaining these standards against the pressure toprovide access to effective treatmentsearlier and without surplus expenditures. In order to provide expedited access to the newest effectivetherapies for critically ill patients in the safest way possible, the FDA has developed several acceleratedpathways to fast-track drug approval. Through partnerships with industry and academic institutions,research is being conducted into how information technology can be integrated into the drug developmentprocessto improveits cost-effectiveness

**ORGANISATION:**

Until the early 1900s, drug products were able to be sold with false labels describing unregulatedingredients as well as unsubstantiated claims about their therapeutic merit. In 1906,

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Congress passed thefirstmajorconsumerprotectionlawcalledthePureFoodandDrugAct,whichprohibitedtheinterstate sale of misbranded food and drugs with regard to their ingredients and purity. This was followed in 1912by the Sherley Amendment, which outlawed the labeling of drugs with false therapeutic claims. Theselaws were enforced by the Bureau of Chemistry in the Department of Agriculture, which became the FDAin 1930.

The next major landmark in drug regulation came in 1938, when the Food, Drug, and Cosmetic(FD&C) Act was passed. This was prompted by the events of 1937, during which 105 people died as aresult of taking elixir sulfanilamide. A Tennessee drug company, S.E. Massengill Co., developed the drugby formulating sulfanilamide, the first sulfa antimicrobial, with diethylene glycol in order to produce aliquid form of the antibiotic. However, diethylene glycol, a derivative of ethylene glycol, which is nowused in antifreeze formulations, is toxic to humans and causes metabolic acidosis, nephrotoxicity, andneurotoxicity. The subsequent public outcry led to the passage of the FD&C Act, which included manynew provisions focused on ensuring that a drug's safety was established prior to a product being releasedon themarket.

The next major enactment came in 1962, when the Kefauver–Harris Amendment was passed.This bill required drug manufacturers to prove that their product was both effective and safe, prior torelease on the market, and to report any adverse effects observed during the post marketing period to theFDA. It also stipulated that the drug's effectiveness be demonstrated in well-controlled clinical trials andthat the patients in those trials must provide informed consent prior to their inclusion. Additionally, itallowed the FDA to control prescription drug advertising in order to ensure the accurate reporting of sideeffects.ThisamendmentenabledtheFDAtorequire"adequateandwell-controlledinvestigations"demonstrating substantial evidence of efficacy11 and established the blueprint for conducting randomizedcontrolledtrials, whichremainthebenchmark fordemonstratingdrugefficacyand safetytoday.

In 1983, the Orphan Drug Act was passed and provided incentives like market exclusivity andtax credits to promote the development of drugs aimed at treating rare diseases. Similar legislation hassincebeen adopted inJapanand theEuropean Union.

In 1992, the Prescription Drug User Fee Act was passed by Congress. This allows the CDER tocollectfeesfromdrugcompaniestobeusedtoboostthe resourcescommittedtowardtheapprovalprocessof aspecificdrug.Inreturn,agreedstagesoftheapprovalprocess mustbecompletedbydeadlines determined at the time at which the fee is collected. This procedure helps the FDA to bringdrugstothemarketina timelyfashion withoutsacrificingthe carefulreviewprocess.

In1998,theAdverseEvent ReportingSystem(AERS)wasintroducedtoenhancepostmarketingsurveillance. This online database allows for the reporting of adverse effects of drugs identified bypatientsor prescribers.

In2000,theClinicalTrials.govwebsitewasmadeavailabletothepublic.Thiswasmandatedbythe 1997 FDA Modernization Act, which required the National Institutes of Health (NIH) to improvepublic access to information about ongoing clinical trials. This database registers all efficacy trialsconductedunder aninvestigationalnew drug(IND) designation.

The FDA Amendments Act of 2007 broadened and updated several previously enacted laws. Thisincluded expanding post marketing safety activities by upgrading the AERS database and analytical toolsand creating the Risk Evaluation and Mitigation Strategies (REMS). program. This program is intended tomitigate risk by allowing the FDA to require drug manufacturers to introduce additional safety provisionswhen the FDA has concerns about a particularly serious adverse event for a specific drug. Examples ofREMS stipulations include the completion of a mandatory proadministration laboratory test if it isexpected to predict the risk of an adverse event or the mandatory immediate availability of a certaintreatment atthe facility where adrugisbeing administered.

In May 2018, the Right to Try Act was signed into federal law. This allows physicians to apply forexpanded access to drugs that have completed a phase I trial but which have not yet been approved by theFDA for market entrance. This law allows patients to bypass FDA approval in the pursuit of expandedaccess.(15)

**VOLUME II: OFFICE OF NATIONAL DRUG CONTROL POLICY(ONDCP)**

The Office of National Drug Control Policy (ONDCP) is responsible for creating,

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implementing,and evaluating U.S. drug control policies to reduce the use, manufacturing, and trafficking of illicit drugsaswellas drug-related healthconsequences, crime,and violence.

ONDCPis located in the ExecutiveOffice ofthePresident.Itwas created by the Anti-DrugAbuseActof1988 and mostrecently reauthorized by theOfficeofNationalDrug ControlPolicyReauthorization Act of 2006. Authorization of appropriations for ONDCP expired at the end of FY2010,but it continues to receive funding. The ONDCP director must develop a National Drug Control Strategy(Strategy)todirectthenation'santidrugeffort s—
andacompanionNationalDrugControlBudget(Budge t)—
andevaluatetheimplementationoftheStrategybyagen ciescontributingtotheFederalDrug Control Program and the outcomes (reducing illicit drug use and its consequences). In addition, ONDCPmanages the High Intensity Drug Trafficking Areas (HIDTA) program and other programs, includingDrugFree Communities (DFC).(14)

**VOLUMEIII:DRUGENFORCEMENTADMINI STRATION**
**"DEPARTMENTOFJUSTICE"**

The mission of DEA is to enforce the controlled substances laws and regulations of the UnitedStates of America and to bring to the criminal and civil justice system of the United States or anyothercompetentjurisdictionthoseorganizations,a ndprincipalmembersoforganizations,involved in the growing, manufacture, or distribution of controlled substances appearing in ordestined for illicit traffic in the United States; and to recommend and support nonenforcementprograms aimed at reducing the availability of illicit controlled substances on the domestic andinternationalmarkets.

In carrying out its mission, DEA is the lead agency responsible for the development of overallFederaldrugenforcementstrategy,programs,p lanning,andevaluation.DEA'sprimaryresponsibilitie sinclude:

1. Investigation and preparation for prosecution of major violators of controlled substanceslaws operating at interstate and international levels in keeping with established drugpriority goals;
2. Management of a national narcotics intelligence system in cooperation with Federal,State,localandforeignofficialstocollect, analyze,anddisseminatestrategicandoperational intelligenceinformation;
3. Seizure and forfeiture of assets derived from, traceable to, or intended to be used forIlletdrug tracking;
4. Enforcement of the provisions of the Controlled Substances Act as they pertain to themanufacture,distribution,and dispensingoflegallyproducedcontrolled substances;
5. CoordinationandcooperationwithFederal,Statea ndlocallawenforcementofficialson mutual drug enforcement efforts and enhancement of such efforts through exploitation ofpotentialinterstateandinternationalinvestigati onsbeyondlocalorlimitedFederaljurisdictionsan d resources;
6. Coordination and cooperation with other Federal, State, and local agencies, and withforeign governments, in programs designed to reduce the availability of illicit abuse-typedrugs on the United States market through nonenforcement methods such as crop eradication;cropsubstitution, and training offoreign officials.
7. Responsibility,underthepolicyguidanceoftheSe cretaryofStateandU.S.Ambassadors, for all programs associated with drug law enforcement counterparts in foreigncountries;and
8. Liaison with the United Nations, INTERPOL, and other organizations on matters relatingtointernational narcoticscontrol programs**. (10)**

**DRUGSCHEDULING:**

Drug scheduling became mandated under The Federal Comprehensive Drug AbusePrevention and Control Act of 1970 (also known as the Controlled Substances Act). The lawaddresses controlled substances within Title II. Based upon this law, the United States DrugEnforcement Agency (DEA) maintains a list of controlled medications and illicit substances thatare categorized from scheduled I to V. The five categories have their basis on the medication'sproper and beneficial medical use and the medication's potential for dependency and abuse. Thepurpose of the law is to provide government oversight over the manufacturing and distribution ofthese types of substances. Prescribers and dispensers are required to have a DEA license tosupplythesedrugs. Thelicensing provideslinks to

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users, prescribers, anddistributor.

**Issuesofconcern:**

The schedules range from Schedule I to V. Schedule I drugs are considered to have thehighest risk of abuse while Schedule V drugs have the lowest potential for abuse. Other factorsconsidered by the DEA include pharmacological effect, evidenced-based knowledge of the drug,risktopublichealth,trendsintheuseofthedrug,and whetherornotthedrughasthepotentialtobe mademoredangerous with minor chemicalmodifications.

**ScheduleI**:
"High abuse potential with no accepted medical use; medications within this schedule maynotbe prescribed, dispensed, oradministered"[1] Examplesofincludemarijuana(cannabis),heroin,mescaline(peyote),lysergicaciddiethylamide(LSD), methylenedioxymethamphetamine(MDMA),andmethaqualone.

**Schedule**II:
"High abuse potential with severe psychological or physical dependence; however, thesemedicationshaveanacceptedmedicaluseandmaybeprescribed,dispensed,oradministered"[1]

Examplesincludefentanyl,oxycodone,morphine,methylphenidate,hydromorphone,amphetamine,methamphetamine (meth), pentobarbital, andsecobarbital. schedule IIdrugsmay notreceivearefill at thepharmacy

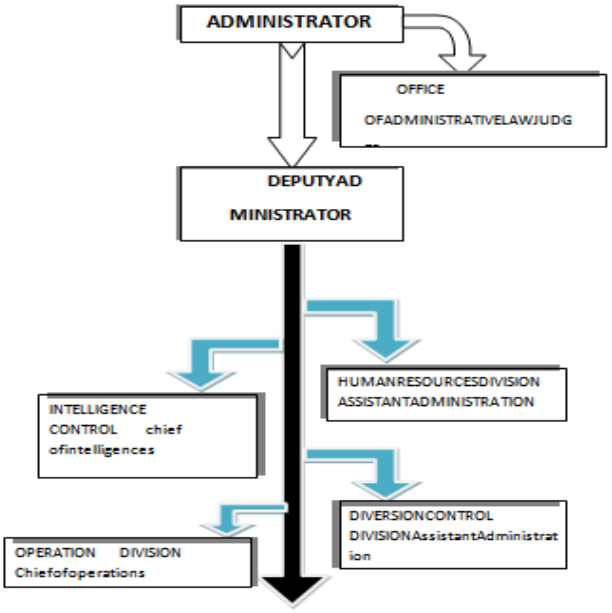
**Schedule**III:
"Intermediateabusepotential(i.e.,lessthanScheduleII butmorethanScheduleIVmedications)examples include anabolicsteroids,testosterone, and ketamine

**ScheduleIV**:
"AbusepotentiallessthanSchedule IIbutmorethanSchedule Vmedications"examplesincludediazepam, Alprazolam,andTramadol

**ScheduleV:**
"Medicationswiththeleastpotentialforabuseamongthecontrolledsubstances."Examples include Pregabalin, Diphenoxylate/Atropine, Dextromethorphan (9)

**EnforcementTrends:**

Trends in federal drug enforcement may reflect changes in the nation's drug problems andchanges in the federal response to these problems. These trends also may reflect the federalgovernment's enforcement priorities. For example, as shown in Figure 4, the number of drugcasesfiledbyU.S.Attorneyssteadilyincreasedinthelate1990sandearly2000s.Whilethismay reflect a higher drug crime incidence rate, it also may reflect a federal enforcement focus ondrug crimes. This section provides a snapshot of federal enforcement trends over the last severaldecades.



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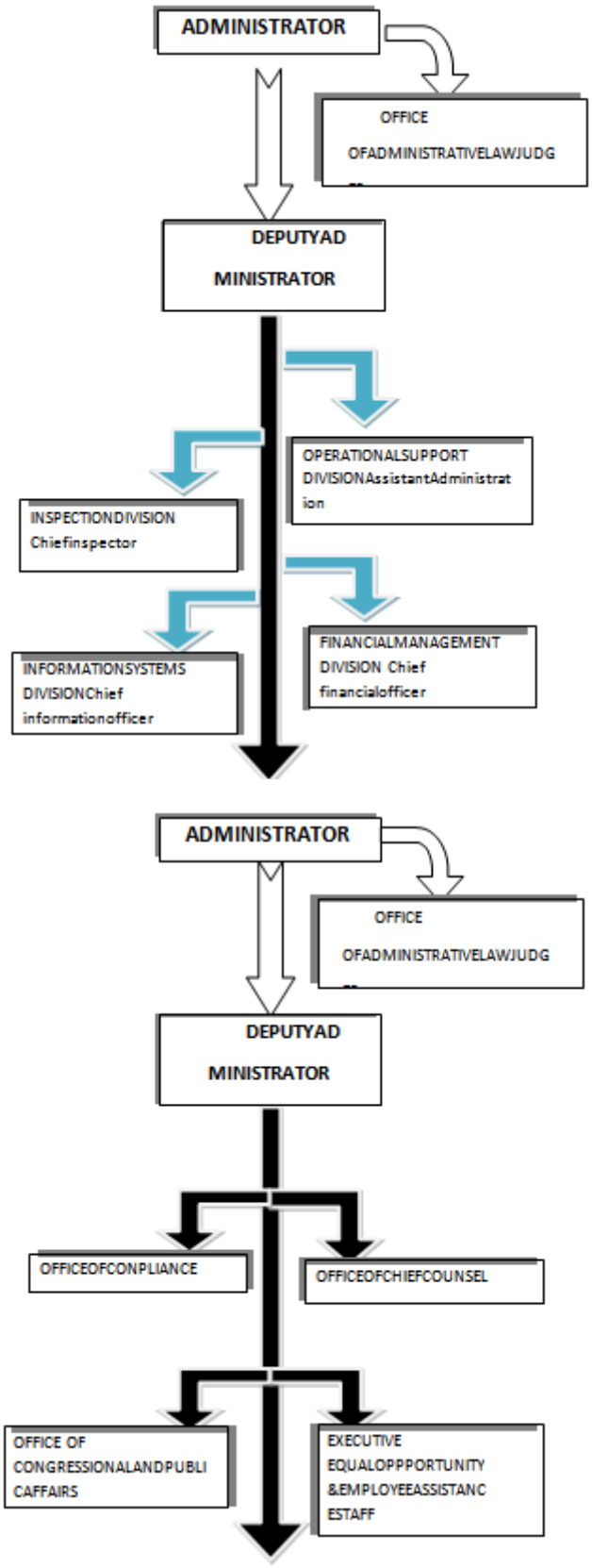

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**FederalDrugArrestsandSeizures**

**Arrests:**

Most drug arrests are made by state and local law enforcement, and most of these arrestsare for possession rather than sale or manufacturing.130 In contrast, most federal drug arrests arefor trafficking offenses rather than possession.131 While multiple federal agencies (as previouslyidentified in this report) engage in federal drug enforcement, the DEA is the primary federalagencyresponsiblefortheenforcementoffederaldruglaws;therefore,itistheagencyoffocusinthis section.(11)

**THERISKOFACTIONBYTHEDRUGENFORCEMENTADMINISTRATIONAGAINSTPHYSICIANSPRESCRIBINGOPIOIDSFOR PAIN**

**INTRODUCTION:**

The under treatment of pain has been well documented and barriers to improving thetreatment have been described. Fear of governmental actions against doctors for prescribingopioids for treatment of pain is one of the barriers. A study of state medical board actions againstphysicians who prescribe opioids for patients in pain found that this fear of state medical boardactions is exaggerated. The actual risk of an American physician being disciplined by a statemedical board for treating a real patient with opioids for a painful medical condition is virtuallynonexistent. In addition to fear of state medical boards, physicians fear an investigation or actionby the federal Drug Enforcement Administration (DEA). The present study was conducted todeterminetheriskofanactionbytheDEAagainstphysicianforprescribingopioidsforpatientsin pain.

**ACTIONTAKENBY DEA:**

Forty-sevendoctorswerearrestedbytheDEAin2003.Thealleged violations leading to the arrests are summarized below. Examples provided bythe DEAare:

- Prescriptionsinexchangeforsex:Wrote prescriptionsfor female membersofmotorcyclegangs in exchangeforsex.
- Prescriptionsformoney:Wroteprescriptionsfor moneyindressingroomsofadultnightclubs.
- Prescriptionsforpersonaluse:UsedDEAregistrationtowritefraudulentprescriptionsinotherindividual names for own personal use.
- Internetprescribing:Wroteprescriptionsforpatientswithoutmedicalexaminationandfordrugs specifically requested by patienton theInternet.
- NolicenseorDEAnumber:Wroteprescriptions afterstatelicensewassuspended.
- Fraudulentprescriptions:UsedDEAregistrationtofraudulentlyobtaindrugsfromwholesalers.
- Prescribedforaddictsorundercoveragents:Wrote prescriptionstoundercoveragentsinexchangefor money.

Manyofthecasesinthissummarydidnotcitethedrugsinvolvedbutonly“controlled substance” so we could not ascertain whether opioids were the principal drugs inthese cases. Others list multiple drugs including an opioid. The allegations in the case notessupplied were sufficient for us to think that 37 doctors were prescribing opioids outside of theacceptable practice of medicine or for their own personal use. Other case notes were too brief forustoindependentlydeterminewhetheranyofthesecasesrepresentedactualmedicalpractice.Six were undercover buys, often multiple times for each doctor, one was for prescribing for drugabuserswith10deathsresultingfromtheprescribeddrugs,onewasforprescribingacontrolled substance after DEA registration was suspended, and two were for unlawful distribution of acontrolledsubstance

The Federal Register cases for 2003 and 2004 included 56 physicians who had their DEACertificates of Registration revoked by the DEA, which initiated the action. Examples of theoffenses include: fraud such as Medicare fraud or fraudulent personal injury claims, prescriptionsin exchange for sex, substance abuse by the prescriber, felony conviction of owning and being onashiptraffickinginheroinandcocaine,prescribingwithouteverseeingthepatients(suchasover the Internet), prescribing after one’s state medical license had been suspended or revoked,and other controlled substance violations. Arrests and convictions occurred prior to medicallicense revocation in some cases. In these cases, the medical appropriateness of the prescribingwas the issue. For example, Gabriel Sagun Orzame, MD: in the DEA’s order revoking hiscontrolled substance registration, itdescribed a criminal complaintinvolving “32 counts ofdelivery of a controlled substance prescription form. Four undercover officers made undercovervisits to the Respondent’s office and he never performedexaminations on them. Nevertheless,the Respondent provided prescriptions for controlled substances for the undercover officers

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andforotherpersonswhowerenotthere".Thesealsoinclude:Dr.Beprescribedcontrolledsubstances to undercover law enforcement personnel and to drug abusers; Dr. Bo prescribedopioidswithoutadequatemedicaltesting;Dr.Jprescribedcontrolledsubstancesfornolegitimatemedical purpose;and Dr.Lwasunlawfully prescribingcontrolledsubstances.(16)

## II. CONCLUSION:

Many in the Regulatory Affairs Profession believe the New Approach to regulation willeventually be adopted for all healthcare products as it represents the best model for deliveringnewhealthcareadvancestomarketinareasonabletimewithacceptablesafety. RegulatoryAffairsdepartmentisconstantlyevolvingandgrowingandistheonewhichisleastimpacteduringtheAcquisitionandMerger,andalsoduringrecession.RegulatoryAffairsdepartmentsaregrowingwithincompanies.Duetothechangingresourcesnecessarytofulfiltheregulatoryrequirements,somecompaniesalsochoosetooutsourceorouttaskregulatoryaffairstoexternal service providers. In today's competitive environment the reduction of the time takes to reach themarket is critical to a product's and hence the company's success. The proper conduct of itsRegulatoryAffairsactivitiesisthereforeofconsiderable economicimportanceforthecompany.

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