

# A NEW PRESCRIPTION TO BALANCE SECRECY AND DISCLOSURE IN DRUG-APPROVAL PROCESSES

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*To obtain approval to market a drug, a manufacturer must disclose significant amounts of research data to the government agency that oversees the approval process. The data often include information that could help advance scientific progress, and are therefore of great value. But current laws in both the United States and Europe give secrecy great weight. This Article proposes an obligatory sealed-bid auction of the sensitive information based on the experience with similar auctions in mergers and acquisitions, to balance manufacturers' interest in secrecy and the public interest in disclosure.*

## INTRODUCTION

Protecting trade secrets and other sensitive commercial information is increasingly significant, given their immense economic worth. In today's globalized world, once such information is disclosed to a third party, it irrevocably loses value. In the highly competitive pharmaceutical industry, in which different companies often race to bring similar drugs to market, the knowledge of a competitor's research data might have a particularly decisive impact on the success of the evolving product, allowing for the development of an improved version or even an entirely new drug. Therefore, the pharmaceutical industry strives for strict secrecy in product development.<sup>1</sup>

To market a drug for human use, a manufacturer needs the approval of a competent government agency. The Food and Drug Administration (FDA) determines the drug's safety and efficacy in the U.S. market, and the European Medicines Agency (EMA) does the same in Europe.<sup>2</sup> Approval requires intensive trials in several specific phases.<sup>3</sup> Approval takes years and costs a fortune.<sup>4</sup> It requires a

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1. Peter Lurie & Allison Zieve, *Sometimes the Silence Can Be Like the Thunder: Access to Pharmaceutical Data at the FDA*, 69 *LAW & CONTEMP. PROBS.* 85, 85 (2006).

2. See *infra* Parts I.B.1., I.C.1.

3. See *id.*

4. See *infra* Part I.B.1.

manufacturer to provide the respective agency with detailed information on the developed drug, particularly the trial and research data.<sup>5</sup> Although parts of the application are publicly available, the current legal framework and its implementation by the FDA and EMA strongly protect sensitive information.<sup>6</sup>

Protecting sensitive information ensures the manufacturer benefits exclusively from its research, and functions as a strong incentive for further investments in research and development, advancing medical science in general. However, by denying competitors and independent scientists access to certain research data, this protection slows scientific progress, since third parties are restrained from using this data to contribute to future innovations. Aligning these conflicting interests implicates public health, because it would contribute to the advancement of medical science. Current proposals to deal with this dilemma tend to lean heavily on one side or the other. Neither approach optimizes scientific progress: one course stifles progress, while the other compromises the incentive to invest in research.<sup>7</sup>

This Article suggests a new approach, advocating that policymakers take advantage of the fact that a government agency is in a position to provide valuable sensitive information to third parties to foster scientific progress. On this basis, this Article proposes an obligatory auction of the sensitive data—a new approach to striking a balance between the private interest in secrecy and the public interest in disclosure in drug-approval processes. This auction shall take place immediately after the drug is approved to market and be conducted by the relevant agency in a strictly regulated proceeding. To amplify the impact on scientific progress, the data shall be disclosed to at least the two highest bidders, with the number of winning bids dependent on the total number of bidders. Preventing abuse of confidentiality, unauthorized use of the data, and secret agreements among the bidders is particularly important. Besides severe monetary sanctions, breaching parties may also be excluded from future auctions. Information substantially important to a manufacturer's business will not be part of the auctioned data. The auction model will not implicate current law, including patent law or the Freedom of Information Act (FOIA).

Part I of the Article defines “sensitive information” and describes the current handling of sensitive information in the U.S. and European drug-approval processes by outlining the general approval

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5. See *infra* Parts I.B.1., I.C.1.

6. See *infra* Parts I.B.2., I.C.2.

7. See *infra* Parts II.C.–E.

procedure and exploring the legal framework and its implementation regarding information disclosure. Part I also demonstrates that the suggested new approach can be applied to both U.S. and EU processes. Part II describes and evaluates the private and public interests involved and analyzes current and other possible approaches. Finally, Part II discusses the auction model in detail.

## I. CURRENT LAWS IN THE U.S. AND EUROPE

### A. Defining “Sensitive Information”

The term “sensitive information,” for the purposes of this Article, is construed broadly and comprises all information that is kept secret by the manufacturer, has a commercial value to its owner because of such secrecy, and must be disclosed to government agencies during the drug-approval process. “Sensitive information,” as defined here, does not refer to data that are part of patents registered during the approval process. The auction model will not interfere with the legal regime of patent law and its method of making information available.

A “secret,” for purposes of this Article, is “a piece of information that is intentionally withheld by one or more social actors from one or more other social actors.”<sup>8</sup> “Commercial value” includes secret aspects of information that provide a company with an advantage over its competitors because of said secrecy. This Article restricts the definition of “sensitive information” to information that has to be disclosed to the relevant government agency, because the government agency is only in these cases in a position to dispose of the information.

The so-called “clinical trial protocol” and the protocol amendments are typically particularly valuable among the information required for the application process<sup>9</sup> for a medicinal product, according to the standard of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH standard).<sup>10</sup> They contain

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8. See KIM LANE SCHEPPELE, LEGAL SECRETS: EQUALITY AND EFFICIENCY IN THE COMMON LAW 12 (1988).

9. See *infra* Parts I.B.1., I.C.1.

10. See *infra* Part I.C.1.

detailed information on a trial's objective and purpose, design, selection and withdrawal of subjects, and methods employed,<sup>11</sup> as well as precise information on the toxicological and pharmacological effects of the product that is far more detailed than information needed for a patent application.<sup>12</sup> This information is of significant strategic interest for competitors.

The term "sensitive information" is used instead of "trade secrets" to avoid ambiguity, given the disputed scope of "trade secrets"<sup>13</sup> and the legal consequences the qualification as "trade secret" implicates (although the predominant definition is interpreted broadly, and includes basically all information that is kept secret and thus provides competitive value to a company).<sup>14</sup>

## *B. Sensitive Information in the U.S. Drug-Approval Process*

### 1. General Drug-Approval Procedure

The FDA drug-approval process<sup>15</sup> begins with submitting a completed Investigational New Drug (IND) application to the FDA that contains information on animal pharmacology and toxicology studies, manufacturing information, clinical protocols, and investigator information.<sup>16</sup> Prior to submitting this application, the drug's manufacturer must, among other things, conduct preclinical animal tests for pharmacological activity and acute toxicity potential.<sup>17</sup>

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11. See EUR. MED. AGENCY, GUIDELINE FOR GOOD CLINICAL PRACTICE 31–34 (2002), available at [http://www.emea.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500002874.pdf](http://www.emea.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf).

12. See ESTHER PEAFF, EXKLUSIVITÄT UND ZUGANG ARZNEIMITTELRECHTLICHER ZULASSUNGSINFORMATIONEN 52 (2009); Roger A. Yates, *Conduct of Clinical Trials: Good Clinical Practice*, in THE TEXTBOOK OF PHARMACEUTICAL MEDICINE 239, 246 (John P. Griffin & John O'Grady eds., 2006).

13. See, e.g., Dawn Rudenko Albert, *Trade Secrets in the United States*, INTELL. ASSET MGMT., July/Aug. 2010, at 93, available at <http://www.iam-magazine.com/issues/article.ashx?g=e85a7dee-1c0f-42e0-8573-6cf922e57c1d>.

14. Cf. UNIF. TRADE SECRETS ACT § 1(4), 14 U.L.A. 538 (2005) ("'Trade secret' means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.")

15. The following shall describe the standard and most common course of the FDA drug-approval process, leaving out, for instance, variations for specific types of drugs.

16. *Investigational New Drug (IND) Application*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm> (last updated June 6, 2011).

17. See *id.*

Consideration of the application proceeds if the testing shows “sufficient hints of drug efficacy” to conclude that testing in humans is warranted.<sup>18</sup> The preclinical phase usually takes three to four years to complete.<sup>19</sup>

Upon approval of the IND application, the “investigative” drug enters three phases of clinical trials. Phase I roughly characterizes the drug’s safety and profile by testing the drug on twenty to eighty volunteers who are usually healthy.<sup>20</sup> If the studies prove that the drug is not inordinately toxic—which approximately two-thirds do<sup>21</sup>—the manufacturer may proceed to Phase II.<sup>22</sup>

In Phase II, the manufacturer conducts well-controlled, closely monitored clinical studies on several hundred patients with the disease or condition that the drug is intended to cure or improve. These studies obtain preliminary data on the drug’s effectiveness, common short-term side effects, and risks.<sup>23</sup> If closer examination of the drug’s toxicity does not suggest further risks and preliminary evidence indicates the drug is effective, the sponsor may proceed to Phase III.<sup>24</sup>

In Phase III, large-scale, randomized trials are conducted on several hundred to several thousand people to gather additional information on the drug’s effectiveness and safety. This information is needed to evaluate the overall benefit-risk relationship.<sup>25</sup> The results of the Phase III clinical trials typically form the essential basis for the FDA’s decision to approve the new drug. Only approximately 10 percent of medications fail Phase III.<sup>26</sup>

The drug’s sponsor then submits a New Drug Application (NDA), the formal proposal to the FDA to approve a new pharmaceutical for sale and marketing in the United States.<sup>27</sup> An NDA and its accompanying documentation are meant to tell “the drug’s whole story,”<sup>28</sup> particularly results and special occurrences during pre-clinical and clinical trials, the drug’s ingredients, how the drug behaves in the body, and how it is manufactured, processed, and

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18. Lurie & Zieve, *supra* note 1, at 87.

19. Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug-Approval Process*, 14 J. AM. BOARD FAM. PRAC. 362, 364 (2001).

20. See FDA, *supra* note 16.

21. Lipsky & Sharp, *supra* note 19, at 365.

22. Lurie & Zieve, *supra* note 1, at 87.

23. See FDA, *supra* note 16.

24. See *id.*

25. See *id.*

26. Lipsky & Sharp, *supra* note 19, at 366.

27. *New Drug Application*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last updated May 18, 2012).

28. *Id.*

packaged.<sup>29</sup> An NDA can easily encompass up to one hundred thousand pages<sup>30</sup> and contains vast amounts of information. It enables FDA reviewers to assess

- whether the drug is safe and effective for its proposed use(s) and whether the benefits of the drug outweigh its risks;
- whether the drug's proposed label is appropriate, and if not, what the drug's label should contain; and
- whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, dosage, quality, and purity.<sup>31</sup>

The review process of an NDA is generally completed within a year or, if the drug is deemed to be a "significant improvement compared to marketed products," within six months.<sup>32</sup>

The whole approval process typically takes a considerable amount of time. Getting a drug onto pharmacy shelves may take up to fifteen years from the start of its development.<sup>33</sup> The average costs are estimated to range from under \$100 million up to \$2 billion<sup>34</sup> depending on the study. This calculation does not take into account that only a fraction of drugs developed in laboratories proceed to human testing, and that only about 20 percent of the compounds tested in humans will be approved by the FDA.<sup>35</sup>

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29. *Id.*; see also Lurie & Zieve, *supra* note 1, at 88.

30. ELAINE WHITMORE, DEVELOPMENT OF FDA-REGULATED MEDICAL PRODUCTS: PRESCRIPTION DRUGS, BIOLOGICS, AND MEDICAL DEVICES 46 (2d ed. 2004).

31. FDA, *supra* note 16.

32. Lurie & Zieve, *supra* note 1, at 88; see also *Fast Track, Accelerated Approval and Priority Review*, FDA, <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm#priorityreview> (last updated Aug. 2, 2012).

33. See Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 94 (2004). Other sources state eight to twelve years. See Lipsky & Sharp, *supra* note 19, at 364.

34. See MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 46 (2004) (estimating costs of "well under \$100 million"); Christopher Paul Adams & Van Vu Brantner, *Spending on New Drug Development*, 19 HEALTH ECON. 130, 141 (2010) (over \$1 billion); Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really \$802 Million?*, 25 HEALTH AFF. 420, 420-27 (2006) (\$500 million to \$2 billion); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003) (\$802 million).

35. Joseph A. DiMasi, *Risks in New Drug Development: Approval Success Rates for Investigational Drugs*, 69 CLINICAL PHARMACOLOGY & THERAPEUTICS 297, 298-305 (2001).

## 2. The Legal Framework Regarding Disclosure and Its Implementation

The legal framework pertaining to the disclosure of sensitive information in drug-approval documentation is complicated and confusing. Relevant provisions are scattered throughout several statutes and regulations, including the Code of Federal Regulations (CFR), the Freedom of Information Act (FOIA),<sup>36</sup> the Federal Food, Drug, and Cosmetic Act (FDCA),<sup>37</sup> the Federal Trade Secrets Act (FTSA),<sup>38</sup> and the Federal Advisory Committee Act (FACA).<sup>39</sup> This section focuses on the most important provisions and their implementation by the FDA, without going into too much detail regarding their content and interrelationships.

The legal framework governing sensitive information disclosure did not provide for substantial automatic disclosure of the application documentation until the Food and Drug Administration Amendments Act of 2007 (2007 FDAAA).<sup>40</sup> Before 2007, one could only find cursory information and some details about the label and approval history on the FDA homepage (e.g., drug labels submitted by the producer and the FDA's letters to the producer).<sup>41</sup> But the 2007 FDAAA brought significant changes.

Section 801 of the 2007 FDAAA requires that the FDA include more information in a clinical trial registry databank, which includes data from trials for drugs, biological products, and medical devices, in accordance with the consensus data elements set of the World Health Organization.<sup>42</sup> However, section 801(j)(2)(A)(ii) specifies the information required to be included in the databank. That section explicitly excludes information of Phase I clinical investigations,<sup>43</sup> which prevents competitors from finding out about a new product in an early stage and selling the product earlier than the original manufacturer. Despite the detailed list of information that must be included in the database, the amount of trial data that

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36. See *infra* notes 44–57, 60 and accompanying text.

37. See, e.g., *infra* note 61 and accompanying text.

38. See *infra* notes 58–59 and accompanying text.

39. See, e.g., *Federal Advisory Committee Act*, FDA, <http://www.fda.gov/RegulatoryInformation/Legislation/ucm161158.htm> (last updated Aug. 17, 2009).

40. See, e.g., ERIN D. WILLIAMS, CONG. RESEARCH SERV., RL 34465, FDA AMENDMENTS ACT OF 2007 (P.L. 110-85) 12 *passim* (2008). The FDA still need not publish the content of Center for Drug Evaluation and Research (CDER) evaluations on why a specific drug has been approved or other details of the application data unless someone requests that data. See *infra* text accompanying notes 43–51.

41. See, e.g., ERIN D. WILLIAMS, *supra* note 40, at 12, 36, 83.

42. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 801 (j)(3)(D)(vi), 121 Stat. 823, 912 (2007).

43. See § 801 (j)(1)(A)(iii).

must be disclosed is quite unclear. In particular, provisions regarding the trial protocol leave room for interpretation. Pursuant to section 801(j)(3)(D)(iii)(III), “[t]he full protocol or such information on the protocol for the trial *as may be necessary* to help to evaluate the results of the trial” is required.<sup>44</sup>

Section 801(j)(6)(A) also includes an important limitation on the disclosure of clinical trial information that is protected by the Freedom of Information Act (FOIA). This limitation—5 U.S.C. § 552(b)(4), which excludes “trade secrets and commercial or financial information obtained from a person and privileged or confidential” from the disclosure requirement—is particularly relevant in this context. The essential question is, what falls under “trade secrets” and “privileged or confidential commercial information” pursuant to FOIA?

A nearly identical issue arises regarding the scope of requests for information. According to 21 C.F.R. § 20.20 (a) and (c), which contain the policy on disclosure of Food and Drug Administration Records, the FDA will make the “fullest possible disclosure of records to the public”<sup>45</sup> upon request, “regardless whether any justification or need for such records have been shown.”<sup>46</sup> (Specific provisions concerning the disclosure of the drug application documentation can be found in 21 C.F.R. §§ 314.430 and 312.130.)<sup>47</sup> However, the fullest possible disclosure shall be “consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.”<sup>48</sup> 21 C.F.R. §§ 20.60 through 20.67 contains exemptions from the disclosure obligation that reflect these considerations. For instance, § 20.61 stipulates an exception for “[t]rade secrets and commercial or financial information which is privileged or confidential”—wording identical to that in FOIA.<sup>49</sup> Naturally, an information request pursuant to FOIA raises the same question of interpretation.

When trying to explore the extent of FOIA exceptions, one has to bear in mind FOIA’s objectives. FOIA generally allows public access to all documentation that forms the records of agencies of the executive branch, without the need to show a specific reason for the

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44. § 801 (j)(1)(A)(iii).

45. See 21 C.F.R. § 20.20(a) (2012).

46. See 21 C.F.R. § 20.20(c) (2012).

47. See 21 C.F.R. §§ 312.130, 314.430 (2012).

48. 21 C.F.R. § 20.20(a) (2011).

49. See 5 U.S.C.A. § 552(b)(4) (West 2010).



request.<sup>50</sup> It is thereby meant to foster a transparent relationship between the state and citizens and ensure that government agencies are acting on behalf of the people.<sup>51</sup> In practice, corporations, rather than private citizens, submit the vast majority of FOIA requests.<sup>52</sup>

Courts have yet to clearly define the scope of exceptions to disclosure under FOIA, despite having considered the matter in several cases.<sup>53</sup> The Supreme Court has held that the exemptions in 5 U.S.C. § 552(b) (4) do not constitute an absolute bar to disclosure.<sup>54</sup> Determining whether certain information constitutes a “trade secret” or “commercial information” requires balancing private and public interests.<sup>55</sup> With commercial information, the decisive consideration often seems to be whether the disclosure is likely to “cause substantial harm to the competitive position of the person from whom the information was obtained”<sup>56</sup>—part of a two-pronged test to define “confidentiality.”

The courts and the FDA typically interpret exceptions to FOIA rather broadly, which favors secrecy.<sup>57</sup> Hence, documentation in the drug-approval process that manufacturers identify as a trade secret or as otherwise commercially relevant is not commonly disclosed to the public. Although the plain text of the legal framework suggests otherwise, sensitive information included in the documentation for drug approval is well protected because of the courts’ and the FDA’s expansive interpretation of the exceptions to FOIA.

50. See *FOIA.Gov*, U.S. DEP’T OF JUSTICE, <http://www.foia.gov/about.html> (last visited Nov. 3, 2012).

51. *Id.*; Bertrand Wägenbaur, *Der Zugang zu EU-Dokumenten—Transparenz zum Anfassen*, EUROPÄISCHE ZEITSCHRIFT FÜR WIRTSCHAFTSRECHT 680, 680 (2001).

52. Eric Lipton, *Republican Congressman Proposes Tracking Freedom of Information Act Requests*, N.Y. TIMES, Jan. 28, 2011, <http://www.nytimes.com/2011/01/29/us/politics/29issa.html>; see also Andreas Theuer, *Der Zugang zu Umweltinformationen aufgrund des Umweltinformationsgesetzes (UIG)*, NEUE ZEITSCHRIFT FÜR VERWALTUNGSRECHT 326, 333 (1996).

53. See, e.g., *Chrysler Corp. v. Brown*, 441 U.S. 281, 290–91 (1979); *Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 901–02 (D.C. Cir. 1999); *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1286–87 (D.C. Cir. 1983); *Pub. Citizen Health Research Grp. v. Nat’l Inst. of Health*, 209 F. Supp. 2d 37, 43–44 (D.D.C. 2002); *Pub. Citizen Health Research Grp. v. FDA*, No. Civ.A. 99-0177(JR), 2000 WL 34262802, at \*4 (D.D.C. 2000); *Pub. Citizen Health Research Grp. v. FDA*, 997 F. Supp. 56, 60–61 (D.D.C. 1998); *Citizens Comm’n on Human Rights v. FDA*, No. 92CV5313, 1993 WL 1610471, at \*9–10 (C.D. Cal. 1993); *Teich v. FDA*, 751 F. Supp. 243, 252–54 (D.D.C. 1990). For a detailed evaluation, see Mustafa Ünlü, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, 16 MICH. TELECOMM. & TECH. L. REV. 511, 525–35 (2010).

54. See *Chrysler Corp.*, 441 U.S. at 291–92; Ünlü, *supra* note 53, at 525.

55. See *Chrysler Corp.*, 441 U.S. at 293.

56. *Pub. Citizen Health Research Grp.*, 704 F.2d at 1290–91.

57. See Janene Boyce, *Disclosure of Clinical Trial Data: Why Exemption 4 of the Freedom of Information Act Should be Restored*, 2005 DUKE L. & TECH. REV. 3, at ¶¶ 16–19.

The FTSA further restricts disclosure. Pursuant to 18 U.S.C. § 1905, any government employee shall not disclose confidential information acquired in the course of employment “in any manner or to any extent not authorized by law.”<sup>58</sup> To be “authorized by law” requires that the party demanding disclosure establish “a nexus between the regulations and some delegation of the requisite legislative authority by Congress.”<sup>59</sup> According to the Supreme Court, FOIA does not meet this requirement.<sup>60</sup> In practice, however, this limitation on disclosure is not as restrictive as it first appears. The FFDCA’s labeling requirements, for instance, constitute an authorization by law allowing a disclosure.<sup>61</sup>

Despite the FDA’s restrictive disclosure policy, threats to the secrecy of a manufacturer’s sensitive information remain. Congress and its committees and subcommittees cannot be denied access to any information related to the drug-approval process on the basis of trade secrecy.<sup>62</sup> This poses a risk to sensitive information, as members of Congress might openly discuss trade secrets under the protection of the Speech or Debate Clause.<sup>63</sup> And the mere fact that the FDA possesses confidential information heightens the risk of disclosure. Given that the FDA has to handle a huge amount of data, which has to be stored, analyzed, and, in part, passed on to other government agencies, companies, or the public, accidental disclosure of confidential information cannot be ruled out and has happened in the past.<sup>64</sup>

### C. Sensitive Information in the European Drug-Approval Process

The handling of sensitive information in the European drug-approval process closely resembles that in the U.S. process. The drug-approval process in the European Union is governed by two main objectives: “safeguarding public health<sup>65</sup> and advancing the

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58. See 18 U.S.C.A. § 1905 (West 2012).

59. *Chrysler Corp.*, 441 U.S. at 304.

60. *Id.* at 303–04.

61. See *id.* at 306 n.38; Ünü, *supra* note 53, at 536.

62. 21 U.S.C. § 331(j) (Supp. 2012).

63. See *Wearly v. Fed. Trade Comm’n*, 462 F. Supp. 589, 600 n.13 (D.N.J. 1978) (referencing Senator Joseph McCarthy’s “practice” of making public disclosures of protected information under the protection of the Speech or Debate Clause); Elizabeth A. Rowe, *Striking a Balance: When Should Trade-Secret Law Shield Disclosure to the Government?*, 96 IOWA L. REV. 791, 817 (2011).

64. See *Jerome Stevens Pharm., Inc. v. FDA*, 402 F.3d 1249, 1251 (D.C. Cir. 2005); *Myers v. Williams*, 819 F. Supp. 919, 920 (D. Or. 1993); Rowe, *supra* note 63, at 815–16.

65. Directive 2001/83, of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, Recital 2,

development of the pharmaceutical industry and trade in medicinal products within the European Community.”<sup>66</sup> The approval process is divided into a centralized and a non-centralized procedure on the European level and exists alongside national approval processes. Because the vast majority of new drugs are registered via the centralized procedure, the following section will focus solely on that procedure.

## 1. General Drug Approval Procedure

Regulation (EC) No 726/2004, regarding “procedures for the authorisation and supervision of medicinal products for human and veterinary use,” provides a detailed legal framework for the EU approval process. The centralized drug-approval process on the European level starts with an application to the European Medicines Agency (EMA) to authorize the medical product.<sup>67</sup> To facilitate the entire process, the EMA strongly encourages applicants to discuss any procedural or regulatory issues on the proposed submission with the EMA before applying.<sup>68</sup> The applicant must also notify the EMA of its intention to apply and provide a “realistic estimate” of the date of submission at least seven months before submission,<sup>69</sup> which enables the EMA to prepare for the authorization proceedings. This notification must therefore include a fair amount of information on the new drug to give the necessary overview of its characteristics.<sup>70</sup>

Article 6 lists the documents required for the application for authorization. To enhance the efficient organization of the approval procedure, applicants must use the EU Common Technical Document (CTD).<sup>71</sup> The CTD is an internationally approved format for presenting data necessary for drug approval within the ICH regions

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2001 O.J. (L 311) 67; Regulation 726/2004, of the European Parliament and of the Council of 31 March 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, 2004 O.J. (L 136) 1.

66. Directive 2001/83, 2001 O.J. 67; Regulation 726/2004, Recital 8 2004 O.J. (L 136) 3.

67. Regulation 726/2004, art. 4(1), 2004 O.J. (L 136) 9.

68. See EUR. COMM’N, ENTER. & INDUS. DIR.-GEN., PROCEDURES FOR MARKETING AUTHORISATION: CENTRALISED PROCEDURE 10 (2006), available at [http://ec.europa.eu/health/files/eudralex/vol-2/a/chap4rev200604\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-2/a/chap4rev200604_en.pdf).

69. See *id.*

70. For a detailed list of desired information, see *id.* at 10–11.

71. EUR. COMM’N, ENTER. AND INDUS. DIR.-GEN., MEDICINAL PRODUCTS FOR HUMAN USE: PRESENTATION AND CONTENT OF THE DOSSIER 2 (2005), available at [http://ec.europa.eu/health/files/eudralex/vol-2/b/part1a\\_userguide\\_03-2005\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-2/b/part1a_userguide_03-2005_en.pdf).

of Europe, the United States, and Japan.<sup>72</sup> It consists of five modules that cover, among other things, the new drug's quality and documentation of non-clinical and clinical trials.<sup>73</sup>

Once submitted, the EMA's Committee for Medicinal Products for Human Use (CHMP)<sup>74</sup> verifies whether the application complies with Directive 2001/83/EC.<sup>75</sup> In accordance with Article 7(a) of Regulation 726/2004, the Committee also examines whether the application satisfies the conditions for granting a marketing authorization, which relate to "the quality, safety, and efficacy of a medicinal product."<sup>76</sup> A valid application must be reviewed within 210 days after receipt;<sup>77</sup> the time limit is reduced to 150 days for medicinal products of major interest for therapeutic innovation.<sup>78</sup> The CHMP completes its review by issuing an opinion in the name of the EMA regarding the admissibility of the product.<sup>79</sup> This opinion is sent to the European Commission, the EU Member States, and the applicant within fifteen days of being issued, and is accompanied by a report that describes the "assessment of the medicinal product" and states the reasons for the CHMP's conclusions.<sup>80</sup>

The Commission then prepares a draft of its decision with respect to the application, which is forwarded to the Member States and the applicant.<sup>81</sup> If the Commission favors granting the marketing authorization, the draft should include or reference the CHMP's summary of the product's characteristics, details of any conditions or restrictions on the medical product, any recommended conditions or restrictions on its safe and effective use, and the draft text of the labeling and package leaflet proposed by the applicant.<sup>82</sup> The Member States are then allowed to comment on the draft and call for a plenary discussion.<sup>83</sup> The Commission's final decision on the application is due within fifteen days of the end of this procedure.<sup>84</sup> The Commission's marketing authorization is valid throughout the European Community for five years,<sup>85</sup> with the

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72. PROCEDURES FOR MARKETING AUTHORISATION, *supra* note 68, at 18.

73. *Id.*

74. Regulation 726/2004, art. 5(1), 2004 O.J. (L 136) 10.

75. *Id.* at art. 7(a), 11.

76. *Id.* at art. 12(1), 14.

77. *Id.* at art. 6(3), 11.

78. *Id.* at art. 14(9).

79. *Id.* at art. 5(2), 10.

80. *Id.* at art. 9(3), 12.

81. *Id.* at art. 10(1), 13.

82. *Id.*

83. *Id.* at art. 10(3), 13.

84. *Id.* at art. 10(2), 13.

85. *Id.* at art. 13(1), 14.

opportunity to renew for an unlimited period after a re-evaluation by the EMA.<sup>86</sup>

## 2. The Legal Framework Regarding Disclosure and Its Implementation

Within the past ten years, the EMA has developed a system of electronic databases on medicinal information known as EU Telematics.<sup>87</sup> An important database for the purposes of this Article is the publicly accessible “EudraPharm” database.<sup>88</sup> It includes a Summary of Product Characteristics (SPC), which informs health-care professionals about how to use the product safely and effectively,<sup>89</sup> as well as the Package Leaflet, which contains basically the same information but is more understandable to laypeople.<sup>90</sup> A separate databank contains the so-called European Public Assessment Report (EPAR), which the EMA publishes immediately after granting its approval.<sup>91</sup> The EPAR includes the EMA’s reasons for granting the authorization and a “summary written in a manner that is understandable to the public.”<sup>92</sup> But Article 13(3) of Regulation No. 726/2004 limits the disclosure of sensitive information, stipulating that any information of a “commercially confidential nature” must be deleted upfront.<sup>93</sup> Neither the regulation itself nor the legislative history provide for any further explanation on how the term “commercially confidential nature” should be understood. As one cannot fully compare the EPAR’s original, full version and the published version without information of a “commercially confidential nature,” the EPA’s policy of protecting sensitive information can hardly be assessed. However, since pharmaceutical companies help generate the data, one can presume a generous attitude towards the industry’s requests regarding the deletion of potentially sensitive information.

Article 13(2) also stipulates that the marketing authorization of a new drug shall be published in the Official Journal of the European

86. *Id.* at art. 14(1)–(3), 15.

87. EUROPEAN MEDS. AGENCY, INTRODUCTION TO THE EU TELEMATICS PROGRAM 3–5 (2010).

88. *See* Regulation 726/2004, art. 57(1)(l), 2004 O.J. (L 136) 36.

89. *Summary of Product Characteristics Definition*, EUDRAPHARM, <http://eudrapharm.eu/eudrapharm/glossary.do> (last visited August 9, 2012).

90. *Package Leaflet Definition*, EUDRAPHARM, <http://eudrapharm.eu/eudrapharm/glossary.do> (last visited Aug. 9, 2012).

91. *See* Regulation 726/2004, art. 13(3), 2004 O.J. (L 136) 14.

92. *Id.*

93. *Id.*

Union and shall specify the “date of authorisation, the registration number in the Community Register, any International Non-proprietary Name (INN) of the active substance, the pharmaceutical form, and any Anatomical Therapeutic Chemical Code (ATC).”<sup>94</sup>

With regard to the disclosure of drug application information upon request, European law provides for a general right of information against the European institutions similar to the FOIA<sup>95</sup> in Article 2 of Regulation (EC) No 1049/2001.<sup>96</sup> However, Article 4(2) of Regulation (EC) No 1049/2001 stipulates a broad exception, providing that access to documents shall be refused “where disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property.”<sup>97</sup> The EMA adopted this exception with the exact same wording.<sup>98</sup> Given the agency’s broad discretion to interpret whether disclosure would undermine the protection of commercial interests, and the lack of clear guidelines, it is again difficult to assess how this exception is applied in practice. The way private and public interests are balanced in the disclosure of sensitive information in Europe very much depends on the practice of a given agency.<sup>99</sup> Because it appears easy to claim that “commercial interests” exist, and because the parties involved are not consulted (letting the decision fall solely to the agency), the EMA will presumably tend to comprehensively protect the manufacturers’ interest in secrecy.<sup>100</sup>

In sum, the unrequested disclosure of drug application data includes a fair amount of information but is thoroughly filtered for sensitive data. Information requests pursuant to Regulation (EC) No. 1049/2001 are unlikely to lead to a disclosure of sensitive data due to the regulation’s broad exceptions.

### C. Comparison of U.S. and EU Models

The United States and Europe are quite similar in how they handle sensitive information and the entire drug-approval process.

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94. *Id.* at art. 13(2).

95. *See supra* Part I.B.2.

96. Council Regulation 1049/2001, of the European Parliament and of the Council of 30 May 2001 Regarding Public Access to European Parliament, Council, and Commission Documents, 2001 O.J. (L 145), 43.

97. *Id.* at art. 4(2).

98. *See* Rules for Implementation of Regulation 1049/2001 on Access to EMEA Documents of 19 December 2006, art. 3(2)(a), 2 (EMEA Management Board), *available at* [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2010/02/WC500070829.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/02/WC500070829.pdf).

99. Wägenbaur, *supra* note 51, at 684.

100. PFAFF, *supra* note 12, at 218–19.

Both make a fair amount of information accessible to the public on the one hand, and—despite disclosure-friendly wording in relevant provisions—provide for a high level of protection of sensitive information on the other. Both systems attach great importance to the manufacturers' interest in the secrecy of commercially relevant information and are thus simultaneously vulnerable to disregarding the public interest<sup>101</sup> in disclosure. These similarities make it possible to apply the approach suggested below<sup>102</sup> to both the U.S. and European models. Allowing U.S. and European companies to participate in identical processes is particularly desirable, as opportunities for efficiency and scientific advancement increase when more parties are involved. In addition, adopting a multinational solution is appropriate for the increasing globalization of the medical sciences and pharmaceutical industries, and will likely decrease regulatory burdens on corporations.

## II. DEVELOPING A NEW APPROACH

Based upon the foregoing findings, this Part will develop a new approach for the handling of sensitive information in the drug-approval process that strikes a balance between the manufacturers' interest in secrecy and the public interest in disclosure. The starting point shall be an evaluation of these colliding interests, followed by a critique of the existing models in the United States and Europe and a short discussion of other possible alternatives. The section ends with a detailed description and substantiation of the suggested new model.

### *A. Interests Involved in Deciding Whether to Disclose Sensitive Information*

#### 1. The Manufacturers' Interest in Secrecy

The most important interest for manufacturers in keeping application information secret is the commercial value of such information. The knowledge of a competitor's research data can have significant consequences in today's fast-moving pharmaceutical

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101. See *supra* Part I.A.2.

102. See *infra* Part II.F.

market. Lead-time to market—the period during which a manufacturer can exclusively sell a newly introduced drug—is more important and valuable than ever before.<sup>103</sup> Studies conducted by the Federal Trade Commission show that doctors tend to continue prescribing pioneer drugs instead of substitutes that have entered the market at a later time.<sup>104</sup> Publishing new information regarding a medicinal product's risks after its introduction into the market seems to have no discernible effect on how doctors prescribe.<sup>105</sup> Yet the disclosure of sensitive information—particularly research data—to competitors can significantly benefit competitors from a scientific perspective. In a considerable number of cases, competitors can improve and more efficiently carry out studies from current research data regarding new versions of existing drugs or new drugs with comparable components.<sup>106</sup> In this context, one has to consider an important characteristic of the pharmaceutical market: the costs of reproducing a medicinal product on the basis of a known formula are vanishingly low compared to the costs of research.<sup>107</sup> Disclosure might enable competitors to substantially improve existing products and might even lead to the development of new drugs<sup>108</sup> that competitors can bring to market first. Furthermore, research data might reveal information about a manufacturer's product pipeline. In all of these cases, a competitor would gain a free advantage at the expense of the manufacturer. Nondisclosure delays the development of competing generics<sup>109</sup> and might prevent a competitor from bringing a new product to market first.<sup>110</sup>

Manufacturers of innovative drugs have alleged that patents no longer ensure a sufficient monopoly and do not adequately protect

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103. See David B. Ridley et al., *Developing Drugs For Developing Countries*, 25 HEALTH AFF. 313, 315, 318 (2006); cf. Ünlü, *supra* note 53, at 517.

104. Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 852 (1980).

105. LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES AND MATERIALS 339 (2d ed. 2006).

106. Ünlü, *supra* note 53, at 518; see also James T. O'Reilly, *Knowledge is Power: Legislative Control of Drug Industry Trade Secrets*, 54 U. CIN. L. REV. 1, 24 (1985).

107. OLIVER GASSMANN & MARTIN BADER, PATENTMANAGEMENT—INNOVATION ERFOLGREICHE NÜTZEN UND SCHÜTZEN 127 (3rd ed. 2010); PFAFF, *supra* note 12, at 24.

108. HEIDE NEUKIRCHEN, DER PHARMA-REPORT: DAS GROßE GESCHÄFT MIT UNSERER GESUNDHEIT 235 (2006); see also Alix Weisfeld, *How Much Intellectual Property Protection Do the Newest (and Coolest) Biotechnologies Get Internationally?*, 6 CHI. J. INT'L L. 833, 836 (2006).

109. A generic drug is a product that, as compared to a reference product, has the same composition in active substances, pharmaceutical form, and bioequivalence shown through bioavailability studies. See *Generic Product Definition*, EUDRAPARM, <http://eudrapharm.eu/eudrapharm/glossary.do> (last visited Aug. 11, 2012).

110. Ünlü, *supra* note 53, at 517.



their interests, given that drug development cycles have lengthened and the patent exclusivity term is now purportedly too short.<sup>111</sup> Patent law thus arguably offers only a theoretical and ineffective solution to the conflict between a producer's interest in secrecy and the public interest in disclosure.

Competitors might also free ride on a manufacturer's efforts to obtain regulatory approval in foreign markets, if the foreign market allows applicants to refer to existing data of trials that they did not conduct.<sup>112</sup> A competitor could then avoid separate trials and save a considerable amount of money, thereby gaining a competitive advantage over the original manufacturer.

Strict confidentiality of the application information can also protect the manufacturer from attacks against the authorized drug itself. As the research data contains information about the drug's risks and side effects, its non-disclosure minimizes third-party scrutiny.<sup>113</sup> With less detailed knowledge about the research data, the manufacturer's potential liability will be harder to prove and the exposure to legal claims reduced.<sup>114</sup> The manufacturer is also less vulnerable to competitors' efforts to emphasize the drug's weaknesses (e.g., through advertisements).<sup>115</sup>

## 2. The Public Interest in Disclosure

The public interest in disclosure of the data required for a drug approval application has three main aspects: first, disclosure fosters an impartial and objective review of the FDA's<sup>116</sup> approval process; second, it allows practitioners to prescribe drugs in a more tailored fashion and more thoroughly describe risks and side effects to their patients; and third, it advances scientific progress and thereby ameliorates public health challenges.

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111. See Ünlü, *supra* note 53, at 516; Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 348–49 (2007); Kuhlik, *supra* note 33, at 96–97. For more information on European patent law, see generally Ulrich M. Gassner, *Untertagschutz im Europäischen Arzneimittelrecht*, GRURINT. 983, 984 (2004).

112. Ünlü, *supra* note 53, at 517–18; O'Reilly, *supra* note 106, at 23.

113. Ünlü, *supra* note 53, at 518.

114. See Ünlü, *supra* note 53, at 518; Mary L. Lyndon, *Secrecy and Access in an Innovation Intensive Economy: Reordering Information Privileges in Environmental, Health, and Safety Law*, 78 U. COLO. L. REV. 465, 520–21 (2007).

115. Ünlü, *supra* note 53, at 518; Eisenberg, *supra* note 111, at 383.

116. Although the following section refers only to the FDA, the same arguments apply to the EMA.

## a. Impartial review of the FDA approval process

Ensuring the safety and efficacy of medicinal products in the United States mainly lies in the hands of the FDA. Safety and efficacy can only be widely guaranteed if the application process ensures a thorough examination of the provided data. However, without access to the data on which the FDA bases its decision to approve an application, there is no mechanism for an independent review of the FDA's work. Naturally, there is a public interest in the ability to review the work of a government agency, especially one having such a direct impact on public health. Moreover, there are other circumstances regarding the FDA's work that particularly must be considered.

First, because of the vast amount of data, the time pressure of the drug-approval process,<sup>117</sup> the complexity of the matter in question, and the FDA's limited resources, mistakes are inevitable.<sup>118</sup> The FDA simply cannot thoroughly review every single page of a one hundred thousand-page application,<sup>119</sup> and is particularly vulnerable when new scientific information or emerging methodologies require reevaluating an earlier approval.<sup>120</sup>

Second, it will often be difficult for the FDA to assess whether the research data provided by the manufacturer "meet the objectivity standards of the scientific process," especially when certain studies fall in the grey area between objective and clearly fraudulent and dishonest.<sup>121</sup> Involving outside academic researchers does not guarantee an objective process, as there are a number of ways in which manufacturers can influence the results of academic work.<sup>122</sup>

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117. See *supra* Parts I.B.1 and I.C.3.

118. See PFAFF, *supra* note 12, at 28; Jennifer Couzin, *Legislators Propose a Registry to Track Clinical Trials from Start to Finish*, 305 SCIENCE 1695, 1695 (2004); Drummond Rennie, *Trial Registration—A Great Idea Switches from Ignored to Irresistible*, 292 J. AM. MED. ASS'N 1359, 1359 (2004).

119. See ROBERT M. RYDZEWSKI, REAL WORLD DRUG DISCOVERY—A CHEMIST'S GUIDE TO BIOTECH AND PHARMACEUTICAL RESEARCH 147 (2008); Sidney A. Shapiro, *Divorcing Profit Motivation from New Drug Research: A Consideration of Proposals to Provide the FDA with Reliable Test Data*, 1978 DUKE L. J. 155, 158 ("[M]ost FDA reviewers randomly audit certain sections of the several hundred volumes of raw data. They find it impossible, however, to review every page of the submitted information.").

120. See Ünlü, *supra* note 53, at 518; McGarity & Shapiro, *supra* note 104, at 841.

121. Ünlü, *supra* note 53, at 518; see also Wendy E. Wagner & David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research*, 30 AM. J.L. & MED. 119, 122–25 (2004) (discussing quality of data issues that can arise in privately sponsored scientific research).

122. See Catherine D. DeAngelis & Phil B. Fontanarosa, *Impugning the Integrity of Medical Science: The Adverse Effects of Industry Influence*, 299 J. AM. MED. ASS'N 1833, 1833–34 (2008); Joseph S. Ross et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case*

Third, it seems that the medical literature is distorted by the selective publishing of favorable trial results.<sup>123</sup> Studies with negative or inconclusive results are unlikely to be the basis for a report or article, possibly because they are presumed to be uninteresting.<sup>124</sup> Therefore, favorable results of a study will be published in various forms in different journals.<sup>125</sup> Publication bias leads to “overly optimistic portrayals of treatments and interventions” in the scientific literature.<sup>126</sup> Admittedly, the FDA cannot solve this problem, because suppression of adverse test data by a manufacturer causes the FDA to lack important information.<sup>127</sup> Rather, there is a need for obligatory registration of every conducted trial in a centralized database to allow for comprehensive review.<sup>128</sup>

### b. Efficient application of drugs

Disclosing research data of a medicinal product also provides practitioners with deeper insight into the way the product functions and its risks and side effects. Knowledge about when administering a drug showed or did not show a certain effect might enable practitioners to prescribe the drug to their patients in a significantly more efficient manner. It would allow a critical review of the treatment’s value to an individual patient.<sup>129</sup> Insofar as this occurred,

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*Study of Industry Documents from Rofecoxib Litigation*, 299 J. AM. MED. ASS’N 1800, 1800–10 (2008); Shapiro, *supra* note 120, at 164; Wagner & Michaels, *supra* note 121, at 120.

123. See Lisa N. Abaid et al., *Reducing Publication Bias of Prospective Clinical Trials Through Trial Registration*, 76 CONTRACEPTION 339, 339 (2007); Couzin, *supra* note 118, at 1695; Richard Hall et al., *Publication Bias in the Medical Literature: A Review by a Canadian Research Ethics Board*, 54 CAN. J. ANESTHESIA 380, 381–87 (2007); Rennie, *supra* note 118, at 1359; Erick H. Turner et al., *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy*, 358 NEW ENG. J. MED. 252, 254 (2008).

124. See Iain Chalmers, *Underreporting Research Is Scientific Misconduct*, 263 J. AM. MED. ASS’N 1405, 1405–08 (1990); Hall et al., *supra* note 123, at 385–86; Barry M. Massie, *Negative, Neutral, and Discordant Results: What Should an Editor Do?*, 9 J. CARDIAC FAILURE 77, 77–79 (2003); Alexa T. McCray, *Better Access to Information About Clinical Trials*, 133 ANNALS INTERNAL MED. 609, 611 (2000).

125. McCray, *supra* note 124, at 611.

126. Abaid et al., *supra* note 123, at 339.

127. See McCray, *supra* note 124, at 609–10; Turner et al., *supra* note 123, at 256–57; Ünlü, *supra* note 53, at 519.

128. See Abaid et al., *supra* note 123, at 341; Chalmers, *supra* note 124, at 1407–08; Hall et al., *supra* note 123, at 387; McCray, *supra* note 124, at 611–13. Regarding current developments, see Sheetal Parekh-Bhurke et al., *Uptake of Methods to Deal with Publication Bias in Systematic Reviews Has Increased over Time, but There is Still Much Scope for Improvement*, 64 J. CLINICAL EPIDEMIOLOGY 349 (2011). Regarding some of the currently existing databases listing information on drug trials, see *infra* Parts I.B.2 and I.C.4.

129. PFAFF, *supra* note 12, at 52; Abaid et al., *supra* note 123, at 339; cf. Boyce, *supra* note 57, at ¶¶ 1–3, 11–13.

disclosure would improve public health. Admittedly, not every practitioner will necessarily resort to such data, but the availability might still promote a more adequate treatment of a significant number of patients.

### c. Scientific progress

Finally, and probably most importantly, the public interest in the disclosure of research data can be based on the advancement of clinical and medical science resulting from disclosure. Because of the tremendous technological developments that have significantly increased the sophistication of today's studies in life sciences (particularly in genomics), and the sheer amount of data and other information produced, the world is facing unprecedented opportunities for scientific progress.<sup>130</sup> Innovations in computer science and information technology allow for a degree of data evaluation unimaginable just twenty years ago. The new field of bioinformatics and innovative data-mining technologies enable new forms of dataset comparisons and analyses, searches for unknown interrelations, and evaluations of data quality and validity.<sup>131</sup> These insights can lead to a better understanding of the interplay of different factors, reevaluation of a drug's safety and efficacy, and new discoveries. Naturally, these forms of data processing depend on the availability of data. Tapping the full scientific potential of research data and making the best possible use of the current level of technology requires public disclosure of all research data in an organized form. Such disclosure would also rapidly enhance the efficiency and speed of scientific research. Tasks such as trials and combining key components would only have to be conducted once, instead of several times by different parties, and the data generated could be used for new trials. Costs could be significantly reduced.<sup>132</sup> In addition, the need for conducting the same trials multiple times raises ethical concerns, as clinical trials can endanger participants' health while only proving something that is already known.<sup>133</sup>

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130. See Ünlü, *supra* note 53, at 538–41; Weisfeld, *supra* note 108, at 837; *Bioinformatics*, NAT'L CENT. FOR BIOTECHNOLOGY INFO., <http://www.ncbi.nlm.nih.gov/About/primer/bioinformatics.html> (last updated March 29, 2004).

131. See Ünlü, *supra* note 53, at 538–41; Weisfeld, *supra* note 108, at 837.

132. See Ünlü, *supra* note 53, at 544; see also Katherine M. Nolan-Stevaix, *Open Source Biology: A Means to Address the Access & Research Gaps?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 271, 282–83 (2007).

133. See Gassner, *supra* note 111, at 984; Hall et al., *supra* note 123, at 381; Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 FOOD & DRUG L.J. 479, 516 (2004).

Hence, there is a strong and constantly increasing public interest in disclosure. The relationship here between disclosure and secrecy is problematic, however: the greater the manufacturers' interest in secrecy because of a dataset's potential to aid scientific progress and benefit third parties, the greater the public interest in disclosure.<sup>134</sup>

### B. *Evaluating Conflicting Interests*

To evaluate the conflicting interests regarding the disclosure or non-disclosure of sensitive information, one needs to identify the potential effects that promoting the respective interests would have.

Guaranteeing the secrecy of a manufacturer's sensitive information, thereby withholding it from the other market participants, allows manufacturers to benefit extensively from their research.<sup>135</sup> They can generate the maximum profit from their head start in knowledge. Hence, the manufacturer's investment in research and development is best protected by secrecy. Such a protection reputedly constitutes a strong incentive for manufacturers to invest in research and development.<sup>136</sup> They are the exclusive beneficiaries of the results in such a situation. A strict nondisclosure policy for competitors' sensitive data also makes generating one's own findings essential to be able to compete. Disclosing sensitive information would likely decrease manufacturers' willingness to invest in research and development, as such investments would not create a significant competitive advantage. Rather, competitors could access the results without having to bear the costs. Therefore, non-disclosure can serve as a major incentive for investments in research and development that contribute to scientific progress. But the investments will tend to concentrate on areas promising the highest revenues, neglecting research for medication to treat rare diseases and diseases that typically affect low-income or poorly represented populations who cannot afford the medication.<sup>137</sup>

Although it would decrease the manufacturers' willingness to invest, disclosure could foster innovation and advance scientific progress. Favoring a general disclosure of sensitive information would most likely contribute to a more efficient use of existing scientific

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134. See Ünlü, *supra* note 53, at 519; Lyndon, *supra* note 114, at 480–81.

135. Although the manufacturers do not always perform the research themselves, any company that is brought into the research process by the manufacturer will be contractually obligated to keep the results of the research confidential.

136. See *supra* Part II.A.1.

137. See Thomas W. Pogge, *Human Rights and Global Health: A Research Program*, 36 *METAPHILOSOPHY* 182, 185–86 (2005); see also *infra* Part II.F.5.

findings.<sup>138</sup> Making research data publicly available could reduce the costs of research and development considerably. Expensive trials would not have to be conducted again, which would offer independent or state-funded scientists more opportunities for research that expanded on disclosed data.<sup>139</sup> Competitors would also benefit, because their development costs would drop, allowing them to invest more money into research.

In addition, disclosure would enable an impartial review of the drug-approval process, providing for enhanced drug quality and security.<sup>140</sup> It would also help contribute to a more efficient drug application because of the potentially deeper understanding of the drug's functioning by practitioners.<sup>141</sup>

However, a problematic issue to be considered is the interrelation between incentivizing manufacturers to do research and utilizing their scientific findings for further research. If less protection of the manufacturers' investments in research leads to a decreased willingness to invest, there will be fewer scientific trials conducted and less research data produced. This effect might eventually counteract the reduction of research costs that would result from publicizing that data. Assuming that public funding—at least in the long run—could not compensate for a significant decrease in private investments, incentivizing manufacturers to invest in research and development is crucial to the advancement of medical science.

The ideal balance would protect investments in research and development, incentivizing manufacturers to strive for scientific progress. At the same time, it would encourage extensive use of today's technological opportunities to increase the efficiency of medical research and development and substantially accelerate scientific progress toward improving public health. Providing a combination of incentives for the private sector to invest in research and development, while allowing the scientific community and competitors to utilize the results, is thus desirable. A successful model should also enable impartial review of the drug-approval process and a more efficient drug application process.

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138. See *supra* Part II.A.2.c.

139. See *infra* Part II.F.5.

140. See *supra* Part II.A.2.a.

141. See *supra* Part II.A.2.b.

### C. Criticism of Existing Models

Current approaches for handling sensitive information in the drug-approval process show significant insufficiencies in light of the foregoing considerations. As described above,<sup>142</sup> commercially relevant information is generally kept confidential in the United States and perhaps even more so in Europe. The manufacturers' interest<sup>143</sup> in secrecy is clearly assessed as more important than the public interests that would be promoted by disclosure,<sup>144</sup> such as an impartial review of the drug-approval process, more efficient drug application procedures, and advancing innovation by increased research efficiency. This one-sided "balance" basically disregards these public concerns. However, the current model provides for a strong incentive for manufacturers to invest in research and development, which serves the public interest insofar as it fosters scientific progress.

### D. Full Public Disclosure

At the opposite end of the spectrum from complete confidentiality is obligatory public disclosure of the entire application documentation. However, this seems incompatible with upholding the incentive to invest in research and development.<sup>145</sup> Because of the need for private investment in research and development to advance scientific progress,<sup>146</sup> favoring the public interest in disclosure over the private interest in secrecy in such a way would eventually harm the public interest by significantly slowing down scientific progress. Since upholding an incentive for investors is crucial, full public disclosure is not a promising option.<sup>147</sup> Furthermore, it could violate the Fifth Amendment. Sensitive information might constitute property, such that its forced disclosure without compensation may well be an unconstitutional taking, despite the public interest in disclosure.<sup>148</sup>

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142. See *supra* Parts I.B.2 and I.C.4.

143. See *supra* Part I.A.1.

144. See *supra* Part I.A.2.

145. See *supra* Part I.B.

146. See *supra* Part I.B.

147. Commentators who favor full public disclosure include, among others, Ünlü, *supra* note 53, at 544–45, and Allen L. White, *Why We Need Global Standards for Corporate Disclosure*, 69 *LAW & CONTEMP. PROBS.* 167, 183–86 (2006). For a view in favor of more restricted public disclosure see PFAFF, *supra* note 12, at 281–83.

148. See *infra* Part II.F.3.b.4; *cf.* *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1000–01 (1984).

Of course, voluntary disclosure is desirable. There are several voluntary initiatives by the pharmaceutical industry to publish trial data in order to foster scientific progress by providing valuable information in the public interest.<sup>149</sup> This development, and the trend toward further cooperation among drug manufacturing companies and between these companies and independent research institutes,<sup>150</sup> should be encouraged.

#### *E. Nondisclosure for a Limited Period of Time*

Given the criteria described above,<sup>151</sup> an ideal model might protect sensitive information for a limited period of time before making it public, and thus serve as a compromise between the current approach of non-disclosure and complete public disclosure. Depending on the complexity and importance of the respective information, the law could provide for public disclosure a certain number of years after the drug's approval by the FDA.

One advantage of such an approach is that manufacturers are presumably still incentivized to invest in research, since protection of their data for even a couple of years creates considerable value. In the pharmaceutical industry, time is of the essence,<sup>152</sup> and a head start can decide a product's success. A side effect might be even greater pressure to accelerate the development process, thereby hastening scientific progress overall. Naturally, the profits from investments—and with them the incentive to invest—would be lower compared to the situation of complete nondisclosure. At the same time, access to the sensitive information would—although with some years delay—incorporate the information into scientific discourse, enhancing research efficiency.

Given today's pace of scientific advancements, two years constitutes a substantial time period. Increased efficiency largely depends on knowledge of the current status quo in the particular field. One can assume that several different players are working on quite similar aspects in any highly developed and popular area of research. Under these circumstances, it is likely that different parties conduct

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149. See Barbara A. Eckman et al., *The Merck Gene Index Browser: An Extensible Data Integration System for Gene Finding, Gene Characterization and EST Data Mining*, 14 *BIOINFORMATICS* 2 (1998); C. Victor Jongeneel, *The Need for a Human Gene Index*, 16 *BIOINFORMATICS* 1059, 1060 (2000); Alan R. Williamson, *The Merck Gene Index Project*, 4 *DRUG DISCOVERY TODAY* 135, 135 (1999).

150. See PFAFF, *supra* note 12, at 149–52.

151. See *supra* Part I.B.

152. See *supra* Part I.A.1.



similar trials within the nondisclosure period, which would have been unnecessary if the sensitive information had been disclosed earlier. Admittedly, the validity of this objection depends very much on how similar the level of expertise is in the research units of different manufacturers. In any case, this consideration weakens the efficiency argument.

Delayed public disclosure of sensitive information might favor larger, financially stronger pharmaceutical companies. As these companies dispose of more extensive financial, technological, and human resources, they might be able to “catch up” with a smaller manufacturer whose research data has been disclosed. In this case, the financially stronger companies could benefit considerably from the information (e.g., by bringing to market a new or improved product based on the disclosed data). As the information was received for free, the benefit would be gained entirely at the expense of the original manufacturer. This aspect might disincentivize larger companies from investing in their own research, as they could try to rely on profiting from information disclosed by others. Simultaneously, smaller manufacturers might be discouraged from investing, as their potential revenues would be diminished. Both developments would hinder scientific progress and pharmaceutical innovation.

Nonetheless, the non-disclosure of sensitive information for a specific period of time still seems to be more balanced than and therefore preferable to the current approach.

#### *F. The Auction Model*

As it is impossible to keep the manufacturers’ sensitive information secret and disclose it to the public at the same time, a model coming as close as possible to properly balancing competing interests must provide strong incentives for manufacturers to invest in research in spite of a disclosure obligation. To protect the manufacturers’ investment, they need to be compensated for an obligatory disclosure. Fairness dictates that those who can profit the most from the disclosed data should pay this compensation. Presumably, these are the competitors—innovative manufacturers—working in the same field. As a side effect, paying for the information would probably motivate competitors even more to advance innovation, as they would have to try to draw profit from their investment in the data. The competitors will only be willing to compensate manufacturers for sensitive information if they are guaranteed a certain amount of exclusivity. Naturally, they have no interest in supplying

the public with the information. Rather, the more exclusivity they get, the more valuable the research data will be to them.

Access to the research data should be restricted to innovative, brand-name manufacturers. These manufacturers can contribute to scientific progress, whereas generic manufacturers make sure that medicinal products are more affordable in the long run. Given that generics can only be brought to market after a patent's expiration and that patent information is already publicly available, generic manufacturers usually will not be interested in the sensitive data.

Naturally, such an approach would not promote the efficiency of scientific research to the extent that full public disclosure would. The latter would spur significantly more participants to get involved, particularly if independent or state-funded scientists' access to the data is increased. And practitioners would rarely be in a better position to more efficiently apply medicinal products than they are today, as the data will not be publicly available. The chances for an impartial review of the government agencies' work in the approval process will also, at best, be slightly improved by the mere introduction of the auction model.<sup>153</sup> But the model protects incentives for research and fosters more efficient organization and acceleration of scientific progress by providing a restricted number of additional parties with access to the research data.

Allowing independent scientists access to the data for the sole purpose of reviewing a government agencies' authorization process can improve transparency. A restricted form of access could also be given to independent or state-funded scientists for research projects in distinct areas.

When establishing an approach based on the foregoing premises, three fundamental issues have to be dealt with: first, how to determine fair compensation and construct an obligatory disclosure procedure; second, how to ensure an impartial review of the government agencies' approval process; and third, whether and how to provide independent or state-funded scientists with access for research in unrelated areas.

### 1. Procedure to Determine Fair Compensation

A fair level of compensation should come as close as possible to the actual market value of the sensitive information. The market value does not simply correspond with the costs of research for the

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153. See *infra* Part II.F.2.

specific medicinal product. This is because these costs do not reflect past losses for unsuccessful research in other areas, which is an important part in calculating the costs of a successful product. Even more importantly, the value of an innovation cannot be assessed merely by its production costs, since others who spent the same amount on research and looked for the same results might not have succeeded. An innovative idea is hard to predict and not comparable to producing something already known. Its market value appears to be quite difficult to assess, because the value of the information depends on what profit the addressee can or hopes to generate with it. The research data are presumably of substantial value only to competitors that are active in the same field as the original manufacturer and either (1) see potential value in the information that the manufacturer overlooked, or (2) are confident they can develop an improved or entirely new product on the basis of the existing information. Hence, determining the sensitive information's market value requires a deep technical insight as well as an inside perspective as to what competitors assume the information can be used for. The latter rests mainly on risk assumptions regarding further investments in research and development in a specific field.

In light of these circumstances, it seems highly unlikely that experts within the FDA<sup>154</sup> are in the position to determine such value on the basis of the application information before them and their industry insight. They particularly would lack the knowledge to detect potential uses of the application data with regard to other drug development projects of competitors. The easiest solution—determination of fair compensation by competent, impartial government agencies—is therefore unavailable. Rather, the parties in the best position to assess the fair market value seem to be those competitors who think they can profit from the sensitive information themselves. Now, the question is how to make use of this knowledge, taking into consideration that the competitors also have a substantial interest in not divulging the real value they attach to the information in order to pay a preferably low amount of compensation.

An auction model, as it is widely used in mergers and acquisitions,<sup>155</sup> would guarantee a compensation that would at least come close to the actual market value of the sensitive information in most

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154. As the auction model would also be implemented in European law, in the following sections, FDA stands for both FDA and EMA, respectively, for ease of reference.

155. See, e.g. Jonathan Rowley, *How M&A Became a Buyers Market*, FIN. TIMES, Oct. 7, 2012.

cases. According to this approach, auctioning the sensitive information would be obligatory, and it goes without saying that the manufacturers would not be allowed to otherwise disclose or sell the information or bid for the data themselves. Of course, the manufacturers might decide to publicly disclose all application information before the beginning of the auction process, rendering it unnecessary. In mergers and acquisitions, an auction is commonly seen as the method most favorable to the seller of a company because it maximizes revenue, on account of competition between bidders.<sup>156</sup> Since auctions are governed by clear rules, procedures, and deadlines, they ensure transparency, credibility, efficiency, and typically take considerably less time than negotiations.<sup>157</sup>

There are a number of parallels between selling a company and selling research information, which, overall, support adoption of the auction model. In both situations, the seller tries to assess the actual market value, and several interested parties exist who think they can obtain greater or different benefit than the seller from the item on sale. In addition, not all information about the item on sale is publicly available, making it necessary to provide the interested parties with some sensitive information about the object in order to enable them to determine its value.

Of course, there are significant differences. With the research data, the seller continues to use the product himself, the object for sale consists solely of information that the seller is obligated to sell, and a government agency disposes of the relevant data and conducts the auction procedure. But these differences do not detract from the auction model's suitability to determine the data's actual market value.

In addition, the auction process in mergers and acquisitions deals with one basic problem that would typically also arise when determining the market value for sensitive information in the drug application process: maintaining confidentiality while providing necessary sensitive information to potential bidders. Potential bidders need to access sensitive information about the company to determine what the offered company is worth to them. In dealing with sensitive information, their value in the drug-approval process can only be determined based on the specific content of such information. In mergers and acquisitions, so-called "due diligence"—a

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156. ROBERT F. BRUNER, APPLIED MERGERS AND ACQUISITIONS 792, 795 (2004); COMM. ON NEGOTIATED ACQUISITIONS, AM. BAR ASS'N, THE M&A PROCESS: A PRACTICAL GUIDE FOR THE BUSINESS LAWYER 93-94 (2005).

157. BRUNER, *supra* note 156, at 795; COMM. ON NEGOTIATED ACQUISITIONS, *supra* note 156, at 93-94.

structured process of disclosing a certain amount of data to a specific number of interested parties to allow them to review the data<sup>158</sup>—solves this problem. Furthermore, it must be ensured that unsuccessful bidders will not commercially use the sensitive information gained throughout the auction process. To deal with this issue, the auction process in mergers and acquisitions provides for strict confidentiality agreements with harsh sanctions in case of breach.<sup>159</sup> This aspect is particularly important for auctioning sensitive information, as it is impossible to reverse the disclosure of information and might sometimes be difficult to prove any subsequent unlawful use of the data occurred.

#### a. Auctions in mergers and acquisitions

The following describes a typical auction process in mergers and acquisitions on an abstract, simplified level. The starting point is the preparation of a so-called offering memorandum or “teaser,” which includes rather broad information about the company to be sold and is intended to function as an “appetizer.”<sup>160</sup> Next, the seller contacts prospective bidders, who are identified for strategic or financial reasons.<sup>161</sup> If the potential buyers indicate interest, the seller provides the offering memorandum after the seller signs a confidentiality agreement.<sup>162</sup> Sellers often request the submission of a nonbinding value range indicating how much a prospective bidder would be willing to pay before providing the bidder with more detailed information.<sup>163</sup> Based on these nonbinding indications, the seller then chooses the bidders who may participate in the second round.<sup>164</sup> Here, the potential purchasers are given access to a data

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158. SHANKAR GANESAN, *HANDBOOK OF MARKETING AND FINANCE* 68–69 (2012); IAN RATNER, GRANT T. STEIN & JOHN C. WEITNAUER, *BUSINESS VALUATION AND BANKRUPTCY* 283 (2009).

159. For M&A transactions, see generally DONALD DEPAMPHILIS, *MERGERS, ACQUISITIONS, AND OTHER RESTRUCTURING ACTIVITIES: AN INTEGRATED APPROACH TO PROCESS, TOOLS, CASES, AND SOLUTIONS* 176 (6th ed. 2012); DONALD DEPAMPHILIS, *MERGERS AND ACQUISITIONS BASICS: NEGOTIATION AND DEAL STRUCTURING* 13–14 (2011).

160. BRUNER, *supra* note 156, at 796; COMM. ON NEGOTIATED ACQUISITIONS, *supra* note 156, at 104; BRUCE WASSERSTEIN, *BIG DEAL: MERGERS AND ACQUISITIONS IN THE DIGITAL AGE* 746 (2001).

161. BRUNER, *supra* note 156, at 796.

162. BRUNER, *supra* note 156, at 796; WASSERSTEIN, *supra* note 160, at 746; *see also* COMM. ON NEGOTIATED ACQUISITIONS, *supra* note 156, at 97–100.

163. BRUNER, *supra* note 156, at 796; COMM. ON NEGOTIATED ACQUISITIONS, *supra* note 156, at 104–05; WASSERSTEIN, *supra* note 160, at 746.

164. BRUNER, *supra* note 156, at 796; COMM. ON NEGOTIATED ACQUISITIONS, *supra* note 156, at 105; WASSERSTEIN, *supra* note 160, at 747.

room with detailed information that is structured to allow due diligence regarding the target.<sup>165</sup> The seller will also give presentations on its company and answer questions in a questions and answers procedure (Q&A).<sup>166</sup> The second round ends with the request to submit a binding bid, which usually has to be accompanied by a firm financial commitment.<sup>167</sup> The whole proceeding is governed by clear rules regarding, for example, the number of questions in Q&A or the form of bids (e.g., cash or stock). There are strict time limits, particularly regarding the length of the due diligence and the deadline for the binding bid.<sup>168</sup> The bids will either be submitted openly or sealed.<sup>169</sup> In the latter case, the bid amounts are held secret from the other bidders.<sup>170</sup> The participant with the highest bid will be declared the winner followed by final negotiations over the definitive agreement.<sup>171</sup>

#### b. Application of auction procedures from mergers and acquisitions

In light of this basic outline of a typical mergers and acquisitions auction procedure, this section explores which parts of the procedure may be applied to the auction of sensitive information in the drug-approval process, and how this proceeding generally should be designed.

#### i. Role of the FDA

First, the role of the FDA shall be determined. I suggest that the FDA should completely control the auction process to reduce manufacturer influence. In contrast to mergers and acquisitions, where the owner of the target company or its advisors typically conduct the auction process, the case of sensitive information offers the opportunity to organize the whole process through an independent government agency to ensure a more fair and impartial procedure.

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165. BRUNER, *supra* note 156, at 796; COMM. ON NEGOTIATED ACQUISITIONS, *supra* note 156, at 105; WASSERSTEIN, *supra* note 160, at 747.

166. BRUNER, *supra* note 156, at 796.

167. BRUNER, *supra* note 156, at 796; COMM. ON NEGOTIATED ACQUISITIONS, *supra* note 156, at 105.

168. See BRUNER, *supra* note 156, at 796; WASSERSTEIN, *supra* note 160, at 746–47.

169. BRUNER, *supra* note 156, at 793.

170. *Id.*

171. BRUNER, *supra* note 156, at 797; COMM. ON NEGOTIATED ACQUISITIONS, *supra* note 156, at 106–07.

Since government agencies determine the disposition of all application information for the medicinal product, manufacturer involvement is generally unnecessary. Moreover, given that a manufacturer must involuntarily relinquish exclusive commercial use of its sensitive information for the benefit of its competitors, the manufacturer's involvement in the auction seems undesirable because of conflicting interests. The model's efficiency naturally depends on the FDA's resistance to corruption.

The complexity of auctioning information in a drug application seems to be considerably lower than selling a company. A company typically resembles a living organism, with employees; offices and/or production sites; sophisticated internal structures; and numerous relationships with other market participants, suppliers, customers, or banks. This can create numerous legal and practical difficulties in the sales process regarding liability, duties of disclosure, warranties, price calculation, or other issues. And even in an auction, the sale of a company cannot occur without complex negotiations concerning the final agreement. In contrast, auctioning information in a drug authorization application seems to be feasible in a simpler, more standard procedure that lacks negotiations. This makes administration by competent government agencies possible without creating unreasonable costs. There is no need for the manufacturer's involvement, since no negotiations take place in this context. Thus, it is irrelevant that a manufacturer's interests could not be sufficiently represented by a government agency.

## ii. First round

As a first step in the auction process, the FDA may simply continue to disclose the same data that currently accompanies its decisions to approve a drug's marketing in the United States.<sup>172</sup> Participants in the pharmaceutical market are already aware of newly approved drugs and closely follow any publications in this regard. One can assume that this awareness will increase once a manufacturer is obligated to disclose sensitive data pertaining to a recently approved drug to the successful bidders of an auction. Data that are currently disclosed also seem sufficient for market participants to evaluate whether they are interested in further information. Hence, there is no need to separately approach potential buyers with an appetizer like the offering memorandum.<sup>173</sup> In case

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172. See *supra* Part I.B.2.

173. See *supra* Part II.F.3.a.

the FDA seriously doubts that potentially interested parties will not learn of a relevant upcoming auction, it might inform these parties on its own account, without disclosing any further information.

To simplify matters, the FDA should announce the upcoming auction and refer to the published data on its homepage immediately after publishing the approval. The announcement should also stipulate the auction's timeline to ensure structured and fast proceedings. At this stage, the deadline for indicating an interest in taking part in the auction's second round is particularly important.

### iii. Second round

Like in mergers and acquisitions auctions, the second round should provide potential buyers with information necessary to submit a binding bid. As with due diligence preparing a data room, FDA experts should grant a selected group of potential buyers access to a revised version of the complete application documentation. This would include enough information to allow for a realistic estimate of the data's worth—meaning more information than is currently accessible via request<sup>174</sup>—while still keeping the most valuable parts secret. To avoid accidental disclosure of overly sensitive data, the FDA will give the manufacturer an opportunity to review the documentation and to articulate any reasonable concerns that should be considered before disclosure.

The revised version of the application documentation will not amount to a compelling equity story of the kind a seller typically provides to raise bids in mergers and acquisitions auctions. The FDA, given its obligation to remain neutral, is not in a position to prepare such an “advertisement” for potential buyers. But the manufacturer should be given the opportunity to compile a report advertising the information to be auctioned, to achieve higher bids. Naturally, the manufacturer will be liable for any false or misleading information in its report. As the interested parties likely know about the potential value of the information (otherwise, they would probably not be interested in bidding to begin with), such a report should not be obligatory.

There is a danger that interested parties will abuse their knowledge of the sensitive information and try to make use of it without compensation. Two separate mechanisms will help prevent such abuse. First, a nonbinding value range that potential buyers are willing to pay, and proof that a party has the means to pursue research

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174. See *supra* Part I.B.2.



using the data to be auctioned, will accompany each indication of interest. On the basis of this range, the FDA will choose a specific number of interested parties. The concrete number should depend on the total number of parties that express interest to prevent the pool of potential buyers from being unnecessarily limited too early.

Second, the FDA should only disclose further information to interested parties upon executing a strict confidentiality agreement and an agreement stipulating that information acquired during due diligence will not be utilized, in case the party is not among the auction's winners. Both agreements should provide for severe sanctions in case of breach. Besides monetary damages, any breaching party will be excluded from participating in any future auctions for a specified time, depending on the gravity of the breach.

These mechanisms cannot completely prevent abusive use of the disclosed information. In particular, breaches of these agreements will be difficult to prove. Passing on information and using the data can be done quite inconspicuously. These acts typically do not involve a large number of people or a considerable effort, and are therefore quite easy to conceal. It might be especially hard to prove that a scientist's invention resulted from information he learned during the second round of the auction process. And the potential profit to be gained may be substantial.

The FDA seems to be in an excellent position to uncover such breaches, as it will review the application documentation for any new drug that may be based on information acquired during the auction process, and it knows about the participants in the auction's information-gathering phase. Furthermore, the sanctions of not only paying a high fine and possible civil damages, but also exclusion from further auctions, should function as a substantial deterrent. To ensure that a thorough examination of future drug approval documentation will reveal potential unlawful uses of research data acquired by unsuccessful bidders, a specific taskforce of scientific specialists could be formed at the FDA. This taskforce could also be responsible for preparing the aforementioned report. It could be financed through a fee to the FDA that would be determined on the basis of a certain percentage of the bids.

Once participants in the second round are chosen and sign both agreements, they should be given time to review the disclosed data before submitting binding offers by a specified deadline. The length of this review period will depend on the amount of data included but should not exceed a few weeks. Between the end of the review process and the deadline for the bids, the potential buyers should be given a few days, or possibly up to two weeks, to decide

on a binding bid. By submitting their bid, the potential buyers will also agree to the terms of the final agreement provided before by the FDA, which shall be non-negotiable, to increase the transparency of the auction process.

The final agreement will prohibit selling or disclosing the acquired data to third parties,<sup>175</sup> as such behavior would affect the information's value for other<sup>176</sup> successful bidders. The agreement will provide that the bids have to be submitted in cash with a firm financial commitment, to ensure comparability among the bidders. The parties will also agree to keep the amount paid in the auction (each party pays the price of its bid) secret to the extent permitted under the bylaws of the company. There is no value in disclosing the amount of the winning bids. In addition, it might frustrate parties coming first in the auction to realize they paid more than the other prevailing parties for the same thing. The identity of the winning parties might reveal information to their competitors on the direction of their future research. The successful bidders shall also not be informed about their ranking in the auction.

The agreement will also stipulate the number of successful bidders that will be given access to the complete application information. The disclosure shall not be limited to only one interested party with the highest bid but should include up to the six highest bidders, depending on the total number of interested parties as well as the data's apparent potential for innovation. By allowing more than one party to purchase the data, compensation for the manufacturer will probably turn out to be higher, although the parties will consider this limit on exclusivity when determining the data's value. This aspect of the process will provide a further incentive to develop a new product. Furthermore, the more parties try to advance upon the disclosed research data, the higher the chances for results that will contribute to scientific progress and innovation. Of course, at the same time, more of the original manufacturer's competitors will be strengthened. However, this result is justified:

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175. A further restriction regarding nondisclosure towards foreign subsidiaries seems unnecessary. The possibility of using the sensitive information for markets outside the U.S. privileges companies operating globally compared to those operating locally, enabling the former to pay more for the data. However, this aspect does not justify further limitation on the further use of the data. Otherwise, the benefit of innovation would be limited to the U.S. In addition, most pharmaceutical companies act globally in light of the research costs connected with the development of new drugs.

176. Regarding the number of successful bidders, *see infra* next paragraph.

the public interest in innovation outweighs the manufacturer's interest in secrecy insofar as the manufacturer will receive considerable compensation from the auction that will likely approximate the market value of its research data.

#### iv. Sealed bids

A further important detail is that the auction procedure will require sealed bids, allowing only the FDA to see the amounts submitted by the participants. Experiences with auctions in mergers and acquisitions have shown that sealed bids ensure the highest revenues.<sup>177</sup> They are commonly seen as an approach very favorable to the seller.<sup>178</sup> Among others, strategies such as collusion, bluffing, and threats are much less likely to occur.<sup>179</sup> The underlying principle is that a bidder, not knowing what its competitors will offer, has to submit the lowest possible bid that is at the same time higher than those of the other participants. The bidder must expect that everyone is willing to pay what the information is—or each party thinks it is—worth. Since every participant will presumably base its bid on these considerations, the bids will likely equal the actual market value that the respective participants attribute to the sensitive information.

Because of the obligatory nature of the auction, it is particularly important that the model address the obvious danger of secret agreements among the bidders, which could lower the highest bids considerably. Through such agreements, the bidders would circumvent the effect of sealed bids and distort the underlying objective of the auction to determine the fair market value of the sensitive information.

To avert this danger, severe sanctions will be imposed if such an agreement becomes public. Like in antitrust law, which basically deals with the same problem (market participants trying to circumvent fundamental principles of fair competition for their own benefit and to the detriment of others), the sanctions will be, in principle, monetary. The sanctions for particularly severe or repeated violations should include exclusion of the parties in breach

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177. WASSERSTEIN, *supra* note 160, at 746; RONALD WEIHE, INTERESSENKONFLIKTE ZWISCHEN UNTERNEHMENSVERKÄUFER UND MANAGEMENT 41–42 (2003); see also Susan Athey et al., *Comparing Open and Sealed Bid Auctions: Evidence from Timber Auctions*, 126 Q.J. ECON. 207, 210–11, 255 (2011); James C. Cox et al., *Theory and Behavior of Single Object Auctions*, 2 RES. IN EXPERIMENTAL ECON. 1, 21–22, 33 (1982).

178. *Id.*

179. BRUNER, *supra* note 156, at 793.

from further auctions, as suggested earlier as a penalty for breaching the confidentiality agreement.<sup>180</sup>

In light of the difficulties inherent in proving secret agreements between the participants, there should be a second approach to prevent abuse of the auction process by bidders: the FDA experts will, before the beginning of the auction, estimate the minimum value of the sensitive information. This minimum value will assist in identifying unrealistically low bids. It will not be disclosed to the participants, as this, of course, could influence the bids. In case the highest bid is below the set minimum value, the whole auction will be terminated because of the high probability of unlawful agreements among the bidders. This precaution also serves to ensure just compensation for the manufacturer to prevent a possible violation of the Fifth Amendment of the U.S. Constitution or the respective takings clauses in European national constitutions. As previously explained, the sensitive information might amount to trade secrets and could thereby constitute property in the meaning of the Fifth Amendment's Takings Clause.<sup>181</sup> Since disclosing the information to the winning bidders without the owner's consent might constitute a taking, the Fifth Amendment requires a public interest in the taking as well as just compensation for the owner.

The minimum value could also eliminate, before the second round, interested parties whose maximum nonbinding offer is below the minimum value. Although such an offer would be based only on preliminary information, it nonetheless might indicate that a bidder does not understand the true value of the data and therefore will not make optimal use of it from the standpoint of scientific innovation.

v. Auction limited to manufacturers mainly operating  
in the U.S. market

To further avoid potential abuse of the auction model to the detriment of the original manufacturer, the pool of potential participants in the auction shall be limited to U.S. companies and companies realizing the majority of their revenues on the U.S. market. The same shall apply for auctions on the European level, meaning that only European companies and those that realize the majority of their revenues in the European market may participate. Otherwise, it would be almost impossible to monitor and control

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180. See *supra* Part II.F.3.b.3.

181. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1000-04 (1984).

unsuccessful bidders' compliance with their contractual obligations, particularly those regarding secrecy and the prohibition to sell the information to third parties. Foreign companies whose primary market is the United States should be allowed to participate in the auction. Since these parties are dependent on the U.S. market, the FDA will review their future products, giving force to the sanction of not being allowed to take part in further auctions. Foreign companies would also have to agree to the U.S. as the forum for any contractual disputes.

vi. Exceptions for information substantially important to a manufacturer's business

Although complete disclosure of sensitive information to the highest bidders would usually be desirable, there may be cases in which an application contains information that is substantially important to the original manufacturer's business. Disclosing such information to competitors might threaten the manufacturer's existence, for instance, if the data indicates a special method of conducting drug trials that permits significant savings. Sensitive information that affects the core of a manufacturer's business will probably only rarely be included in drug approval applications. In these cases, the manufacturer's interest in keeping such data secret outweighs the public interest in disclosure.

Hence, the manufacturer will first indicate to the FDA which information is not to be disclosed to the public because it constitutes confidential commercial information. Second, the manufacturer may identify which information should not be handed over to the successful bidders. The manufacturer must explain why disclosing this information to competitors threatens the existence of its business. The mere fact that a disclosure may impact the manufacturer's business interests is not sufficient. The FDA will decide whether to exclude the respective information from disclosure. Should the FDA disagree with the manufacturer, it may approach a competent court to rule on the permissibility of disclosure in an interlocutory proceeding.

This exception concerning information of substantial importance for the manufacturer's business is important to strike a fair balance between manufacturers' interest in secrecy and the public interest in disclosure.

## 2. Ensuring Impartial Review of the FDA Approval Process

The suggested model promotes enhanced review of the integrity and quality of research data disclosed by manufacturers at least regarding the parts intended for further use, as they will verify the data before using it for development of their products—if nothing else, to avoid liability. Sometimes, the auction winners might also review other parts of the FDA's work to find possible misconduct by the agency that allows them to challenge the approval and thereby weaken their competitors. However, this motive only applies as long as challenging the approval would not impair the research data they plan to use themselves and have already paid for (giving them a clear commercial interest in the data). Hence, the manufacturers are not suited to ensure impartial review of the FDA approval process. Hence, there remains a need for independent experts to conduct the review. This section outlines a rough framework for independent review, which NGOs, for example, might use to prove the existence of irregularities in the FDA's work. Of course, this framework has to consider the importance of secrecy for incentivizing scientific progress.<sup>182</sup>

The FDA should be obligated to disclose research data upon the request of a person who meets the following criteria: First, that person must dispose of the scientific knowledge, and have the financial means to conduct a thorough and useful review, according to scientific standards. But the applied standard should not be unreasonably high. Second, the person cannot be an employee of or otherwise acquainted with any pharmaceutical company. Otherwise, the person's objectivity would be compromised. Third, the person must sign strict confidentiality agreements prohibiting any disclosure of information gained in connection with the review proceeding except, of course, if the information is necessary to prove the existence of irregularities. Fourth, the inquirer must promise not to use the insights gained through the review proceeding in any way, including for personal research, until the corresponding data are publicly available. One might also require the person to refrain from developing a medicinal product in a related field. Despite the last two restrictions, a risk for unauthorized disclosure remains, especially since a breach will often be hard to prove.<sup>183</sup>

Although this proceeding cannot guarantee absolute secrecy, it constitutes a compromise between the manufacturers' interest in secrecy and the public interest in disclosure, as well as the interest a

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182. See *supra* Part I.B.

183. See *supra* Part II.F.1.b.3.

competitor might have in independent monitoring of the FDA's work.

To allow for a subsequent review of the FDA's work and to make trial data available for the scientific community, complete application data should be disclosed after an extended period of time. Ten years might be adequate to not adversely affect the manufacturer's and the buyers' interests. As a safeguard, the exception for information of substantial importance for the manufacturer's or the buyers' business, as suggested above, should apply at this stage as well.<sup>184</sup>

### 3. Access for Independent or State-Funded Scientists

So far, the auction model has not offered a means to improve independent scientists' access to the drug application data. Naturally, this group cannot compete with private companies in the auction process. Granting this group access would significantly reduce research costs and allow independent and state-funded scientists to further advance scientific progress.<sup>185</sup> In contrast to pharmaceutical companies,<sup>186</sup> independent and state-funded scientists are not focused on generating revenues. Often, their objective lies in researching less explored, less profitable areas, including diseases that are rare or that primarily affect people who cannot afford expensive treatment. This is not to say that such research is always unprofitable or will never be performed by drug companies. However, independent and state-funded research, for example in universities or hospitals, constitutes an integral part of scientific progress and can supplement the pharmaceutical industry's efforts.

A general disclosure to independent researchers would undermine the manufacturer's incentive for investing in research, given that confidentiality among third parties cannot be ensured. Thus, it does not constitute a viable option. As a compromise, one could amend the auction model in two ways. First, the manufacturer could voluntarily hand over the data for free to certain groups of scientists. These groups would not be allowed to publish or otherwise disclose results of their research that could affect the manufacturer's or the buyers' commercial interests. In the case of research in areas in which a private company is not interested—and which therefore does not implicate its interests—disclosure could even be

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184. See *supra* Part II.F.3.c.

185. See *supra* Part II.A.2.c.

186. See Pogge, *supra* note 137, at 185–86.

made mandatory. Second, sensitive data could be disclosed to independent researchers only after a certain period of time, allowing pharmaceutical companies to secure their market position. In both cases, arrangements with independent or state-funded scientists should include confidentiality agreements to prevent unauthorized disclosure. As the first option appears to have an earlier and therefore likely greater impact on advancing scientific progress, it seems preferable over the second option. Admittedly, the latter provides more protection for the pharmaceutical companies and should in any case be implemented, to ensure incentives for investment in research are preserved.

#### 4. More Efficient Use of Drugs

The auction model does not achieve more efficient and appropriate use of medications.<sup>187</sup> However, it seems impossible to grant the public more detailed access to the sensitive data included in the drug application process without jeopardizing the manufacturers' incentives for investments in research and development. This limitation is acceptable, because practitioners and patients can usually become quite well informed via material currently disclosed with regard to medicinal products, particularly the package leaflets that accompany prescriptions. In addition, the trial data, because of its technical content, probably will seldom contain useful insights for lay people. Hence, this aspect of the public interest seems easiest to neglect.

#### CONCLUSION

An auction model would more efficiently balance the private interest in secrecy against the public interest in disclosure of sensitive information contained in drug application documentation. Manufacturers in the U.S. and in Europe should be compelled to disclose the complete documentation required for the drug-approval process (subject to the exceptions mentioned) in auctions supervised by the FDA/EMA. This procedure is in the best interest of scientific progress and superior to the current system for protecting such information in the United States and Europe. Fairly compensating the original manufacturer for sharing its research data with those who can use it to contribute to scientific progress overcomes the

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187. See *supra* Part II.A.2.b.



problem of reducing a manufacturer's incentive to invest in scientific research. Experience with auctions in mergers and acquisitions demonstrates that such an approach can be applied in practice and leads to fair results.