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Toward Greater Transparency at FDA

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Executive Summary

The Food and Drug Administration (FDA) plays a critical role in safeguarding public health through its regulation of human drugs, biologics, medical devices, tobacco products, food, and veterinary drugs. Yet, despite its scientific rigor and global reputation, the FDA has long faced criticism for being inadequately transparent about regulatory processes, data, and decisions – particularly those that relate to product approval and safety actions.

Public support for transparency is strong and bipartisan, and the new administration has adopted the phrase "radical transparency" to justify some of its policy actions. After reviewing the status of FDA transparency efforts since the external 2017 *Blueprint for Transparency at the US Food and Drug Administration* (hereafter referred to as the *Blueprint*), we conducted 38 expert interviews and a literature review of 115 journal articles, identified through a formal literature search. We summarize our findings in this report to highlight areas of progress, identify persistent gaps in disclosure, and propose actionable steps to improve transparency.

Among the issues highlighted are inconsistencies between the practices of different parts of the agency (typically the result of statutes requiring more transparency in certain areas), particularly with respect to product approval. We also examine best practices used by regulators of other nations, which may inform future efforts at the FDA. In this report, we add 15 new recommendations for transparency to the 17 (of 18) recommendations from the *Blueprint* that have not been fully implemented. In total, this report therefore recommends 32 actions to strengthen transparency efforts at FDA.

These 32 recommendations could be accomplished by a variety of means. For instance, 3 of these recommendations could be implemented tomorrow by changing FDA's internal norms, 10 would need relatively simple policy changes, while 14 would require updating regulations. While none of the recommendations, with certainty, requires statutory change, 16 of the identified recommendations would benefit from modified statutes to clarify the agency's authority.

One longstanding recommendation for transparency is the release of Complete Response Letters (CRLs) that describe the reasons drugs and biologics are not allowed to be marketed. At the direction of Commissioner Marty Makary, FDA began releasing CRLs for unapproved products in September 2025. FDA had previously taken the position that disclosure of CRLs would require a change in regulation, because disclosure would acknowledge the existence of a New Drug Application (NDA), which the agency has long considered confidential. Without a regulatory change, the current legal basis for CRL disclosure is unclear.

Our most salient recommendations fall into four categories:

EXPAND DISCLOSURE OF MARKETING DENIAL COMMUNICATIONS ACROSS ALL FDA PRODUCT CENTERS

The practice of releasing marketing denials has thus far only applied to drugs and biologics in the form of CRLs. Equivalent documents for products overseen by other FDA centers (devices, animal drugs, and certain tobacco products) are still not publicly disclosed. To promote consistency and transparency, the FDA should extend disclosure of marketing denial communications to all product categories.

ACKNOWLEDGE THE EXISTENCE OF NEW MARKETING APPLICATIONS AND INVESTIGATIONAL PRODUCTS

The decision to now disclose CRLs should prompt a reexamination of the practice of not publicly acknowledging the existence of an NDA. Among other benefits, this would make it easier for FDA to correct misinformation about products under review. To go one step further, disclosure of investigational products, information of considerable interest to researchers, clinicians, and investors, would further open to the door to release of clinical holds and refuse-to-file letters.

IMPROVE FDA PROCESSES TO ENHANCE TRANSPARENCY

Transparency can be significantly improved through updates to FDA's document disclosure protocols and database infrastructure. We identified six key documents that, with increased appropriations, should be proactively disclosed instead of waiting for a certain number of requests (typically three) under the Freedom of Information Act before disclosure. In addition, FDA should enhance the accessibility of its often-lengthy, legislatively mandated reports by providing clear conclusions, summary statistics and executive summaries. Upgrades to databases like Drugs@FDA would enable advanced search capabilities and data downloads.

DEVELOP A SYSTEM THAT PROVIDES THE PUBLIC WITH GREATER VISIBILITY INTO WHEN NEW ADDITIVES ARE MARKETED AND INTO THE BASIS FOR CONCLUDING THAT THEY ARE SAFE

A major gap in food safety oversight is the Generally Recognized as Safe (GRAS) loophole, which allows companies to self-affirm the safety of food additives and bring products to market without notifying FDA. The result is a system stark in its lack of transparency—industry's self-attestations of safety are not routinely provided to FDA, and the general public does not even know what additives are being added to the market. Health and Human Services Secretary Robert F. Kennedy, Jr., has expressed an interest in addressing this issue. Such reforms should include both a listing of new additives as well as agency premarket review. The agency has the authority to address this issue through updated regulations, but statutory change, as has been put forth in recently introduced legislation, would also be effective.

Taken together, these reforms would help FDA fulfill its mission more effectively, rebuild public trust, and hold the agency accountable for making science-based decisions, while fostering the dissemination of basic scientific information that could fuel future innovation.

Introduction

The Food and Drug Administration (FDA) is world-renowned for its expertise and scientific review of medical products, but the agency often faces scrutiny of its transparency practices. Calls for enhanced transparency at FDA are grounded in the belief that an open and publicly engaged government functions more effectively and fosters public trust. Transparent systems typically involve clearer public explanations of government action, quicker release of documents and databases, more opportunities for public comment, and an aversion to sudden, unexplained major changes in direction.

These tenets of transparency have the potential to improve perceptions of government agencies such as FDA. For example, describing the agency's internal deliberations or detailed data analyses can help demonstrate the rigor and integrity of its decision-making, rather than leaving the public to fill in the blanks with speculation or misinformation. Conversely, withholding information and the agency's reasoning, whether unintentionally or due to bureaucratic constraints, creates an environment that permits public suspicion that something objectionable is being hidden.

Agency transparency also fosters predictability that benefits medical product innovation and the broader economy. Particularly given that FDA is in substantial part funded by Congressional appropriations,[1] encouraging public understanding of the agency's work reinforces accountability and promotes responsible stewardship of taxpayer resources. In addition, transparency in FDA review processes benefits private-sector stakeholders, particularly investors in the biomedical and pharmaceutical industries. Clear communication about product development regulatory milestones such as trial outcomes or approval decisions facilitates more informed investments.[2] Disclosure of reasons for failure of one set of products can help inform decisions about others, reducing uncertainty and waste, and promoting innovation.

In response to these public health imperatives, FDA convened a Transparency Task Force in 2009, and a group of academic researchers published a *Blueprint for Transparency at the U.S. Food and Drug Administration* (hereafter referred to as the *Blueprint*) in 2017, but progress towards transparency has generally been slow. In this report, we describe transparency efforts at FDA since publication of the *Blueprint*, and, based on expert interviews and a literature review, we examine some of the reasons for the lack of movement. Finally, we make recommendations to advance transparency at FDA, promoting open government and enhancing public trust.

A BRIEF HISTORY OF TRANSPARENCY AT FDA

Attention to the issue of transparency at FDA stretches back decades. In 1977, the Review Panel on New Drug Regulation, a group established by the Department of Health, Education, and Welfare (now known as Health and Human Services [HHS]), released a report evaluating FDA's new drug review process and making recommendations for improvement. The group noted the lack of transparency in the new drug regulation process, primarily due to FDA's own approach to trade secrets, in which FDA pledged to keep from public view all trade secret and confidential commercial information,[3] as defined by Exemption 4 of the Freedom of Information Act of 1966 (FOIA).[4,5] The authors of this report urged lawmakers to "amend the Federal Food, Drug, and Cosmetic Act to provide that scientific data about new drugs belong in the public domain and should not be considered trade secrets."[3] Many of the recommendations from the report were captured in the Drug Regulation Reform Act of 1978 that sought sweeping changes to the drug regulation process,[6,7] including increasing information availability for consumers and increasing FDA's public accountability, but the bill ultimately failed to pass in Congress.[8]

Transparency policies later gained some momentum in the area of clinical trials reporting with the passage of the FDA Modernization Act of 1997 (FDAMA), which required the National Institutes of Health to create a public database for clinical trials, now housed at ClinicalTrials.gov.[9] FDAMA required certain efficacy trials for FDA-regulated investigational new drugs to be registered.[9] Later, with the passage of the FDA Amendments Act of 2007 (FDAAA), Congress mandated clinical trials results reporting,[10] with the reporting requirements going into effect for studies completed on or after January 18, 2017.[11]

Broader transparency efforts received renewed attention under FDA Commissioner Margaret Hamburg (2009-2015), when, in 2009, an internal Transparency Task Force was launched, consistent with President Barack Obama's Open Government Initiative.[12] Among other activities, the agency opened a public docket, convened a public hearing, and solicited input from its employees. The result was a plan with three stages. In the first, FDA established a website called FDA Basics, which provided essential information about agency functions.[12] The FDA Basics home page seems to have been lost in a web host migration in 2019, but some of its subpages (e.g., FDA Basics for Industry) still exist. In the second, the agency established FDA-TRACK, a set of frequently updated performance metrics covering all the agency's major activities, which exists to this day.[12,13] The third was a set of 21 draft proposals put forth by the Transparency Task Force for expanding the disclosure of certain documents or processes, while safeguarding industry trade secrets and confidential commercial information.[12,14] The 21 draft proposals covered a range of FDA operations, and, since the plan's release, nine have been at least partially implemented (see Table 1).

The next major milestone in the field was the publication of the 2017 *Blueprint*, released by a group of academic scholars, including the former Principal Deputy Commissioner at FDA who had chaired the Transparency Task Force.[15] (One author of this report [PL], a former FDA Associate Commissioner, served as a liaison between FDA and the *Blueprint* authors during its development.) The *Blueprint* included 18 recommendations that overlapped with and, in some instances, went beyond proposals made by the FDA Transparency Task Force.[14,15] Of the 21 recommendations issued by the FDA Transparency Task Force, nine have been implemented, most or all by the time of the *Blueprint* (see Table 1). The *Blueprint* incorporated six of the remaining 12, while most of six others were either related to or superseded by other *Blueprint* recommendations or related to food, which the *Blueprint* did not address. For that reason, we use the *Blueprint* recommendations as the starting point for this report.

In 2018, FDA Commissioner Scott Gottlieb (2017-19) announced pilots to address two of these recommendations,[16] the outcomes of which are described in detail in our Finding later in this report that the majority of the *Blueprint* recommendations have not been implemented.

In 2025, the second Trump Administration introduced another wave of public interest in FDA transparency. HHS Secretary Robert F. Kennedy, Jr., and FDA Commissioner Martin Makary (2025-) have made claims about promoting "radical transparency" in the agency, but the result has been a series of haphazard and, at times, contradictory actions.[17] Major changes in FDA's transparency practices in the first nine months of the second Trump administration are described further in the following section.

FDA'S CURRENT TRANSPARENCY PRACTICES

Most prior FDA transparency efforts, including the Transparency Initiative and *Blueprint*, focused on transparency in the context of drugs, biologics, and medical devices, overseen by the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH), respectively, with a particular emphasis on the premarket approval process. (The Center for Veterinary Medicine [CVM] generally follows the same premarket approval processes as these Centers but was not studied in depth in previous reports.) All four Centers have historically treated the filing of a New Drug Application (NDA) or equivalent as confidential commercial information, and the agency does not confirm or deny that an application is pending.[18–21] Except in the relatively uncommon situation when an investigational product is brought before an Advisory Committee (AC), at which large amounts of otherwise proprietary summary data may be shared, this non-disclosure typically continues until the product is approved. For approved products across the major product centers, FDA posts an Approval Package on its website.

For drug and biologic products, reasons denying approval are detailed in a Complete Response Letter (CRL) to the company, which, until recently, were only released at the company's discretion.[22] As is described in more detail in our Finding describing the outcomes of the *Blueprint* recommendations later in this report, FDA began releasing CRLs for unapproved products in July 2025,[23] with plans to release CRLs in real time going forward.[24]

For veterinary drugs, the agency still does not release its findings publicly if the product is not approved.[19] Similarly, for devices, reasons denying approval of applications are detailed in a "not approvable" letter,[25] which is not publicly disclosed.

Despite the change in practice regarding CRLs, a series of non-disclosure policies persists. For example, in the process of considering an investigational product, sponsors may request meetings with FDA, the minutes of which are only released in approval packages. In addition, FDA does not release safety or efficacy information justifying clinical holds (temporary suspensions of clinical trials due to safety concerns or insufficient data), does not disclose whether or why a product has been assigned to certain expedited programs (mechanisms such as Fast Track or Breakthrough Therapy designed to accelerate review of projects addressing unmet medical needs), and, to our knowledge, has never corrected industry misrepresentations of data during the medical product review process. To disclose any of these, in the agency's view, would be to effectively confirm that an NDA has been filed.

Much of FDA's transparency activity has historically been mediated through its various FOIA offices. Under FOIA and FDA's associated procedures, the agency is required to respond to each request, at least initially, within 20 working days.[26] In FY24 alone, FDA received nearly 12,000 FOIA requests.[27] The agency categorizes each request as simple or complex, depending on the amount of search, review, and analysis required, with simple requests being more targeted asks for fewer pages and complex requests seeking a high volume of material that may require additional processing.[28] In FY24, FDA processed and took final action on 81.9% of simple requests and 30.1% of complex requests within the 20-day timeframe.[27] These rates are a substantial improvement over 2008 to 2017, during which only 28.8% of simple and 9.0% of complex requests were processed within that timeframe.[29] Despite these recent gains, FDA ended FY24 with a backlog of 3,967 unresolved requests and appeals,[27] nearly double the number pending at the end of 2017.[29]

In April 2025, shortly into the second Trump Administration, sudden and substantial staff cuts, known as Reductions-in-Force (RIFs), to FOIA staff (some of whom were later reinstated) resulted in several missed court-ordered deadlines to produce documents.[30] Beyond the FOIA department, abrupt dismissals of communications personnel have further impaired the FDA's ability to publicly share information, and one affected staff member questioned how "radical transparency" can be achieved without the necessary communicators to assure it.[31]

In 2025, HHS also created a "Radical Transparency" webpage in which the Department highlights its initiatives meant to advance transparency.[32] These include two FDA initiatives, one of which is a directive to explore rulemaking to close the loophole in which the food industry can self-affirm that food chemicals are generally recognized as safe (GRAS),[33] a process described further in our Findings and Recommendations. In addition, the Department created a Chemical Contaminants Transparency Tool which consolidates regulatory levels for all contaminants levels in a single location for ease of searching.[34] However, the various levels of contaminants presented in this tool were already publicly available.[17,34]

Methods

The Findings and Recommendations in this report were developed using two major data collection strategies: informal interviews with key experts familiar with FDA and its transparency practices, and a literature review. We also convened an Advisory Committee of five experts on FDA transparency who advised on our strategy. The Committee met on two occasions and provided detailed input on a draft report, as well as consultations on specific topics as needed.

KEY EXPERT INTERVIEWS

Key experts ("interviewees") were invited to participate in a 30–60-minute, informal, unrecorded conversation with two of the authors (PL, IPU). These individuals were identified by the authors and the Advisory Committee, and each interviewee was asked for recommendations for additional experts to interview. Interviewees included at least two current or former FDA employees from all six product Centers, the Office of Inspections and Investigations (OII) (formerly the Office of Regulatory Affairs [ORA]), and the Office of the Commissioner (OC) (generally from senior levels), as well as representatives from industry, consumer advocacy groups, and the media. The informants are not identified in this report and interviews proceeded informally, depending on interviewees' areas of knowledge. No personal or health information was sought, and interviewees were guaranteed anonymity. Consequently, the interviews were not considered human subjects research. Interviews took place between August 12, 2024, and May 8, 2025.

In total, 52 potential interviewees were invited to participate, of whom 38 accepted. Conversations were held by phone or video conferencing for 37 of the informants, with one informant providing written comments via email. Contemporaneous notes from these meetings were used to develop codes that were refined in an iterative manner and resulted in a final coding scheme of 100 codes that were organized using ATLAS.ti Web. The final codes were categorized into eight themes, and each interview was coded according to all themes that arose in the interview.

LITERATURE REVIEW

The purpose of the literature review was to identify recommendations regarding FDA transparency in the published literature and additional reports. While not intended to be a formal systematic review, we followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) checklist when developing our search strategy. Search results were managed using Covidence.

We conducted searches using PubMed, Google Scholar and Google Search. We searched PubMed using the following search string: ((transparen*) OR ("Disclosure"[Mesh] OR disclos*)) AND ("United States Food and Drug Administration"[Mesh]). In Google Scholar, we searched for "FDA transparency" and for "FDA disclosure." On Google Search, we searched for "FDA transparency" and for "FDA disclosure" and reviewed result titles and preview text for the first five pages of results. Duplicate titles were removed.

A search for articles available in (or translatable to) English in each database was conducted on March 7, 2025, with no beginning date cutoff. Original qualitative, quantitative, and mixed methods studies, meta-analyses, reviews, public reports, commentaries, opinions, letters to the editor, and conference proceedings or abstracts were included.

One investigator (IPU) independently screened titles and abstracts. Full texts of references deemed relevant were reviewed to identify specific recommendations regarding transparency at FDA. Bibliographic information (author, year, country), abstract (if available), study design (if applicable), key results (if applicable), funding, and author conflicts of interest were also extracted for the included publications.

The PubMed search yielded 1425 results, Google Scholar 687 results, and Google Search 100 results. 104 duplicate titles were removed, 1760 were irrelevant, and 236 were excluded, leaving 112 publications in the review (see Figure 1). Three titles shared by interviewees that were not identified using our search strategy were also added, for a total of 115 titles. The most common reason for exclusion was not including a recommendation for FDA transparency.

The literature review yielded four new topics not identified in the interviews, for a total of 12 themes generated from both data collection strategies. The publications were then organized according to one or more of these themes. The themes form the basis for either the Findings or Recommendations presented in this report.

Findings

RECOMMENDATIONS FROM THE *BLUEPRINT* HAVE LARGELY NOT BEEN IMPLEMENTED

In 2018, FDA Commissioner Scott Gottlieb (2017-19), announced initiatives to address three of the 18 *Blueprint* recommendations: first, the release of Clinical Study Reports (CSRs), which are detailed summaries of pivotal studies for approved drugs; second, the disclosure of CRLs; and third, including ClinicalTrials.gov identifiers on FDA documents to aid cross-referencing.[16] The project to release CSRs took the form of a pilot that initially aimed for the voluntary release of nine CSRs, but resulted in the release of only one,[35] as manufacturers were reluctant to participate. The pilot was discontinued in 2020.[35] The agency had considered structuring CSR disclosures around disclosure formats for similar documents already disclosed by the European Medicines Agency, but ran aground on inconsistent international data and redaction requirements,[36] particularly around privacy.

The second *Blueprint* recommendation identified for implementation was the public release of at least portions of CRLs, a recommendation also made by the earlier Transparency Task Force.[14,15] This project in part explored the additional review time required to redact confidential commercial information and trade secrets from CRLs prior to disclsoure.[16] (While earlier recommendations appeared to apply to all CRLs, including those for generic medications, interest has always been greatest in disclosure for NDAs and perhaps supplemental NDAs.) In a 2019 tweet, Commissioner Gottlieb addressed the status of the project, saying, "Question was: Is that best PUBLIC HEALTH use of scarce medical reviewer time. Need a strong PUBLIC HEALTH reason to allocate it..."[37] (emphasis in original). According to interviewees, internal FDA discussions were consistent with Gottlieb's public tweet, with the agency concluding that disclosing CRLs would not provide enough public health benefit to justify the effort and ultimately abandon the pilot.

Commissioner Makary revived efforts to publicly disclose CRLs in July 2025 when the agency announced the availability of over 200 CRLs in an open database.[23] The vast majority of these CRLs were already available in approval packages because the products were later approved, although others were publicly disclosed for the first time.[38] In September 2025, the agency went further when it released 89 CRLs for unapproved drugs with pending or withdrawn applications dating back to 2024 and announced its intention to release CRLs in real time.[24] The legality of this practice has been questioned. Our own legal analysis, like that of law firms Arnold & Porter[39] and Hyman, Phelps, & McNamara,[40] has found that FDA should update existing regulations to provide clear authorization for disclosing all CRLs, including those for applications that have not been acknowledged by the sponsor.

Historically, the agency has argued that disclosing CRLs would violate its own approach to disclosure by acknowledging the existence of an unapproved NDA or Biologics License Application (BLA), information that was considered confidential. The recent shift in CRL disclosure practice calls FDA's historical justification into question. For, if historically CRLs could not be disclosed because they in effect revealed the filing of an NDA, a decision to disclose CRLs should prompt a reexamination of the practice of considering the filing of an NDA confidential. FDA regulations state that "FDA will not publicly disclose the existence of an application or abbreviated application before an approval letter is sent to the applicant … unless the existence of the application or abbreviated application has been

previously publicly disclosed or acknowledged."[21] But FDA's own research has demonstrated that 97.6% of NDA and BLA filings in 2016, were accompanied by company disclosures in press releases or Securities and Exchange Commission (SEC) disclosures.[41]

The third *Blueprint* recommendation, to include ClinicalTrials.gov identification numbers (NCTs) on disclosures of investigational notices (e.g., Investigational New Drug Applications) and new marketing applications,[15] appears to have been only partially implemented. Following the release of the *Blueprint*, FDA began incorporating ClinicalTrials.gov identification numbers into some agency reviews of NDAs and BLAs, but inconsistently. In our review of 14 randomly selected new drug and biologics approvals between April 2024 and February 2025, nine included ClinicalTrials.gov identification numbers and five did not. As FDA does not disclose investigational notices for drugs, biologics and devices, the use of ClinicalTrials.gov identification numbers in those documents could not be verified.

TRANSPARENCY IS POPULAR WITH THE PUBLIC

Transparency resonates strongly with the public. In a 2022 survey of 1,035 U.S adults, support was at least 65% for each of 10 transparency measures derived from the *Blueprint*, with support generally sustained across political affiliations, genders, races, education levels, socioeconomic statuses, and geographic regions of the U.S.[42] Among these measures, the highest levels of support were for disclosing the reasons new drugs are not approved (i.e., CRLs) (86.2%) and for FDA correcting false or misleading information spread by pharmaceutical companies (90.7%).[42]

Even within the agency, there has been strong support for transparency. Current and former FDA Center Directors Patrizia Cavazzoni, Michelle Tarver, Peter Marks, and former Deputy Commissioner Jim Jones, when asked about transparency at a January 2025 conference on innovations in regulatory science, all endorsed increased transparency for the agency, with particular attention to drug product denials and device safety alerts.[43]

IN CERTAIN RESPECTS, FDA IS LESS TRANSPARENT FOR DRUGS THAN FOR DEVICES, TOBACCO AND FOOD PRODUCTS

While the agency strives for consistency in its transparency practices, statutes relevant to three particular premarket programs require greater transparency than the agency typically provides. In these arenas, FDA has successfully maintained a policy of transparency that exceeds its widely understood premarket application processes.

First, in the device arena, the Medical Device Amendments of 1976 require that the agency disclose a summary of safety and effectiveness data of a device following the denial or approval of its Premarket Approval (PMA) application.[44] Until 2022, denials were published in quarterly Federal Register notices, but in 2022, FDA amended its procedures to disclose denied applications on its website instead.[45] Since that update, based on a review of that website, no devices have apparently been denied approval. Instead, in a step short of official denial, PMAs denied approval to market receive a "not approvable" letter, analogous to a CRL, and that is not disclosed. The 2010 Transparency Task Force and the *Blueprint* recommended changing this practice.[14,15]

Second, Modified Risk Tobacco Product (MRTP) applications, which are for products that claim to reduce the health risk of tobacco products, are subject to a series of transparency requirements. By statute, after withholding trade secret and confidential commercial information, FDA must provide an opportunity for public comment on all MRTP applications and refer the applications to the Tobacco Product Scientific Advisory Committee, which meets in public.[46]

Third, the application process for new food additives under the Food Additive Petition and Color Additive Petition processes is, by law, strikingly public, other than with respect to confidential commercial information and trade secrets. Petitions are announced in the Federal Register within 30 days of filing[47] and all human and animal studies of the food additive are obtainable under FOIA, as are all correspondence and written summaries of verbal discussions relating to the petition.[48] FDA is also more forthcoming about its review of chemicals in the food supply, described in more detail below in our Recommendation to disclose more information about safety investigations.

These islands of transparency, however, have limited scope. For example, by the end of FY24, only 132 applications had been submitted to the more transparent MRTP pathway,[49] and only 24 MRTP authorizations have been granted as of November 14, 2025.[50] In contrast, by the end of FY2024, FDA had received over 26.6 million Premarket Tobacco Product Applications (for conventional tobacco products, including e-cigarettes not making a reduced-risk claim),[49] which are not made public.[51] The Food Additive Petition process appears to have been similarly supplanted by the more secretive GRAS process, further described below.[52]

FDA'S GRAS PATHWAY IS LESS TRANSPARENT THAN FOR OTHER PRODUCTS

The transparent process for food and color additive approvals described in the previous Finding stands in stark contrast to FDA's enforcement of the Food, Drug, and Cosmetics Act's "GRAS provision," established by the Food Additives Amendment of 1958 (FAA).[53] This provision allows companies to self-certify their food chemicals as being GRAS and to bring them to market.[54] Originally intended as a method for not requiring review of longstanding culinary ingredients, GRAS has since expanded beyond its original purpose and is now the predominant pathway for new food chemicals to come to market.[55] FDA received only 12 food and color additive petitions compared to 73 voluntary GRAS notices in FY24.[56]

Companies, however, are not obligated to notify FDA of their assertions that their food chemicals are safe.[54] In 1997, FDA published a proposed rule for GRAS, finalized in 2016, that described optimal processes for companies to voluntarily notify FDA that they had self-determined their chemical to be GRAS.[57] Information provided in such GRAS notices and FDA's final response to companies' applications is available on its website.[58] The ironic impact of this rule was to clarify that GRAS notices were not mandatory.[57] By 2010, an estimated 1,000 manufacturer self-determined GRAS substances, also called "secret GRAS," were already on the market,[59] and, given the voluntary FDA notification, the true magnitude of secret GRAS chemicals in the food supply is unknowable.

TRANSPARENCY IS LIMITED BY LACK OF RESOURCES

Implementation of transparency initiatives requires resources. Nearly half (48%) of FDA's funding in FY24 came from User Fee Agreements,[60] which FDA can spend only on certain programs and activities, including some FOIA activities.[61] The remainder of FDA's budget is appropriated by Congress and supports other fundamental functions of the agency.[60] Scholars have indicated the need for additional funding to expedite responses to information requests.[62]

The elimination of most FOIA offices throughout the agency in March 2025 exacerbated FDA's resource limitations.[63] While some of these positions were reinstated,[30] the prospect of further layoffs and voluntary departures leaves the agency's transparency processes,[30] which included the receipt and processing of nearly 12,000 FOIA requests in FY24,27 with an uncertain future. It is possible that more FOIA requests will be processed at the Department of HHS level, but that approach raises concerns about political interference in what should be a basic bureaucratic process. This potential for politicization was underlined by the retention of staff in CBER's FOIA office, who, in the midst of widespread layoffs, were tasked with document production resulting from a vaccine-related lawsuit brought by the Secretary's campaign lawyer.[64] There is also concern about a loss of efficiency that results when FOIA officers are separated from the agency generating the requested documents.

For FDA to implement any additional transparency practices and policies, more staff would be needed to engage in, among other activities, the time-consuming process of identifying and appropriately redacting documents before public disclosure. It is possible, with the increasingly sophisticated capabilities of artificial intelligence (AI), that FDA could leverage technology to assist with such tasks, and Commissioner Makary seems to have embraced this for increasing efficiency in other parts of the agency.[65] However, according to those interviewed for this report, AI is not yet sufficiently reliable to supplant human review of documents for redaction. In all likelihood, human review of draft AI redactions would still be required.

It seems clear that having *fewer* resources is antithetical to the goal of increased transparency. Recent cuts to federal government staff, including nearly 20% of FDA employees[66] likely including at least some FOIA staff, present challenges for the agency to continue even the scope of its current work.

SEVERAL INTERNATIONAL REGULATORY AUTHORITIES ARE MORE TRANSPARENT THAN FDA

FDA often withholds more information about both authorized and unauthorized products compared to analogous foreign regulatory authorities. For example, a 2021 analysis found that FDA had only ever proactively released clinical summary data (in the aforementioned CSR pilot) for one medical product.[62] In contrast, Health Canada (HC), the analogous regulatory body in Canada, had released clinical summary data for 73 unique medical products between 2019 and April 2021 and these are available in a public database.[62] In Europe, the European Medicines Agency (EMA) released data on 147 unique medical products from 2015 to April 2021.[62]

Of course, the authority for transparency varies by that agency's underlying statutes and policies. The EMA's mandate for transparency is established in Article 15 of the Treaty on the functioning of the European Union and is operationalized in its internal policies.[67] Specifically Policy 0043 allows disclosure upon request (i.e., reactive) of most EMA documents,[67] and Policy 0070 allows for proactive disclosure of clinical study reports and individual patient data.[68] HC's authority is established in law through the 2013 Protecting Canadians from Unsafe Drugs Act (Vanessa's Law), requiring the agency to publicly disclose clinical trial information from sponsors.[69] FDA's authority to disclose information comes from FOIA, bounded by its own regulations elaborating on how it will not disclose confidential commercial information or trade secrets.[4] FDA's CSR pilot attempted to make available clinical summary data disclosed by foreign agencies, but it was abandoned because of inefficiencies resulting from technically different disclosure requirements across regions.[35]

Since FDA's attempt to disclose CSRs, the agency has implemented an integrated review template that, in its view, would improve the navigability of its documents and aid stakeholder understanding of drug approvals.[70] This template, however, has been criticized for its summary nature and the potential loss of granularity from different (and potentially dissenting) voices.[71]

Recommendations

FDA SHOULD IMPLEMENT THE REMAINING RECOMMENDATIONS FOR TRANSPARENCY OUTLINED IN THE *BLUEPRINT*

FDA appears to have fully implemented only one of the 18 recommendations contained in the *Blueprint*, to include NCT numbers on new marketing applications. The agency's recent actions to disclose CRLs for drugs and biologics partially address another *Blueprint* recommendation to disclose FDA communications to companies when products are not approved. But to fully implement this recommendation, FDA should also release analogous documents for unapproved devices, animal drugs, and tobacco products. The release of these documents should proceed legally, including implementing any regulatory changes necessary.

We otherwise do not further revisit the *Blueprint* recommendations in any detail in this report, except as they arise in relevant new recommendations and in the section below addressing FDA authority to implement the recommendations, but the earlier recommendations remain valid.

FDA SHOULD RELEASE ADDITIONAL DOCUMENTS RELATED TO THE PRODUCT-APPROVAL PROCESS

We identified five additional documents related to product approvals that warrant disclosure. These documents fall into two categories: 1) those that are not currently obtainable through FOIA (a below), and 2) those that are currently obtainable through FOIA and for which we recommend proactive disclosure by the agency (b-e below). Proactive disclosure of documents can be done through relatively simple changes in FDA policy. For documents not currently obtainable through FOIA, regulatory or statutory reform may be needed.

a. Refuse-to-File Letters

When FDA receives a product marketing application, it completes an initial "filing review" to assess whether the application is administratively sufficient for full review. If FDA identifies problems with the application, it issues a refuse-to-file letter to the sponsor, specifying these problems, which can relate to quality, safety, and efficacy.[72] While applicants may publicly disclose the existence or content of a refuse-to-file letter themselves, an FDA analysis showed that applicants made public only 15.5% of 103 refuse-to-file letters from 2008-2017; these public disclosures included only 5.4% of the 644 total FDA-identified reasons for the refuse-to-file letters.[72] Disclosure of refuse-to-file letters would help other applicants learn from previous applications' pitfalls, potentially avoiding similar issues going forward. Investors would also likely find this information germane.[72] While refuse-to-file letters are not described in the *Blueprint*, the FDA Transparency Task Force recommended that they be disclosed.[14]

b. Approval packages for supplemental indications

After a drug product has been approved for marketing, the sponsor may later obtain supplemental approval for new indications. Unlike the approval of a drug for its first indication, supplemental indication approval packages are not consistently available on the agency's website. While these packages are accessible via a FOIA request and should be posted if the agency receives at least three requests,[26] supplemental indication approval packages should be treated similarly to approvals of first indications and be proactively posted on FDA's website at the time of approval. Supplemental approval packages are typically substantially shorter than those for initial approvals, but with 257 supplemental NDA and BLA submissions in FY24, compared to 117 submitted NDAs and BLAs for new products,[73] proactive disclosure of these approval packages could be a significant burden without more resources.

c. Preliminary Notices of Noncompliance with clinical trials reporting requirements

Section 801 of the FDAAA established a requirement that the sponsor or principal investigator submit summary results from "applicable clinical trials" of FDA-regulated products to ClinicalTrials.gov, generally within 12 months of the trial's primary completion date.[10] FDA can issue a Preliminary Notice of Noncompliance ("Pre-Notice") when the sponsor or investigator fails to meet the requirement.[74] This notice typically informs the recipient that, if the submission requirements are still not met within 30 days, the agency may initiate a Notice of Noncompliance, civil money penalties, an injunction, and/or criminal prosecution.[74]

Timely reporting of clinical trial results has proven to be a challenge. In a report developed by the Department of HHS, 40.9% (1165 of 2851) of applicable clinical trials reported results late in FY22.[75] Despite this non-compliance, FDA issued only 57 Pre-Notices between 2013 and April 2021; 90% of recipients responded with the missing information within a median of three weeks of receipt.[76]

Pre-Notices are not proactively disclosed to the public, although they can be obtained through a FOIA request.[76] To increase public accountability and to encourage prompt action from trial sponsors, FDA should proactively post these Pre-Notices on its website and include links to the notices at ClinicalTrials.gov.[76]

d. Annual Risk Evaluation and Mitigation Strategies (REMS) Reports

When FDA approves a drug for which there is a major safety concern that could be addressed with targeted prescribing approaches, it can require sponsors to develop such approaches, including additional education of prescribers or documentation of patient testing.[77] These requirements, collectively called Risk Evaluation and Mitigation Strategies (REMS), may also include patient education requirements or required provider trainings.[77] Sponsors are required to periodically report their progress on these requirements[78] and these progress reports may be obtained under the FOIA.[79] Only through such FOIA requests were academic researchers able to identify serious limitations in the effectiveness of opioid-related REMS.[80,81] Because by definition these REMS involve approved products with serious safety concerns, proactive posting of these reports is justified.[80]

e. Periodic Benefit-Risk Evaluation Reports (PBRERs)

After the approval of a drug or biologic product, manufacturers are required by law to report evolving safety and efficacy data to FDA. Since 2016, FDA has allowed industry to do so in the form of Periodic Benefit-Risk Evaluation Reports (PBRERs), a format replacing the previously-used Periodic Safety Update Reports (PSURs).[82] PBRERs contain sections with summaries of safety concerns, potential safety signals, and an evaluation of benefit in light of these risks.[82] PBRERs are only available through a FOIA request, even though this information may benefit patients and providers in understanding the entire body of evidence surrounding a drug product and how that body of evidence is evolving.[83] Given the likely public health and clinical benefits, including for other products for the same condition coming to or already on the market, the agency should proactively release PBRERs.

FDA SHOULD INCREASE THE TRANSPARENCY OF AC MEETINGS BY ENHANCING CONFLICT OF INTEREST DISCLOSURES

FDA Advisory Committee (AC) members must disclose financial conflicts of interest in advance of an AC meeting. "Section 208 conflicts" (regulated under 18 USC § 208) are created by current financial conflicts of interest, while "Section 502 conflicts" (regulated under 5 CFR § 2635.502) are created by past financial interests or personal and business relationships that could create the appearance of a conflict. FDA may exclude a member from participating in an AC meeting based on either type of conflict.[84,85] In the event an individual with a Section 208 conflict is allowed to participate in a meeting, the nature of that conflict is publicly disclosed, typically by the AC's Designated Federal Officer, at the beginning of the meeting and a waiver explaining the rationale for the AC member's inclusion that is posted on the agency's website.[86]

In an FDA analysis, 27.3% of AC meetings with votes on drugs and devices held between 2008 and 2014 included at least one voting member with a Section 502 conflict.[87] These conflicts were not publicly disclosed, although they were not associated with voting behavior in that same analysis.[87] Non-governmental organizations or journalists may identify these 502 conflicts from public records, leading to allegations of undeclared conflicts of interest, even if such conflicts do not run afoul of Section 208. FDA could improve transparency and enhance trust in its ACs by routinely disclosing Section 502 conflicts,[88] potentially inoculating FDA against allegations that conflicts were intentionally withheld and enhancing trust in its ACs. Disclosure of Section 502 conflicts would likely be achieved through changing FDA policy, and in a 2016 draft Guidance, the agency requested public comments on the release of Section 502 conflicts.[89] The Guidance was never finalized.

In 2025, Commissioner Makary began circumventing the established AC process by hosting several external "expert panels" on a variety of specific topics with hand-picked experts.[90] These have typically taken place with very little advanced notice and no opportunity for public participation. In contrast, federal ACs are required by the Federal Advisory Committee Act (FACA) to have balanced membership in terms of points of view, and meetings require at least 15 days advanced notice,[91] opportunities for public engagement, and documentation in the form of detailed meeting minutes.[92] Unlike officially designated ACs, in its first expert panel meeting, FDA did not prompt conflict-of-interest disclosures from invited speakers.[93] In subsequent panels, the agency asked speakers to disclose potential conflicts, but they did so in a manner not consistent with the standardized format in which conflicts are disclosed at AC meetings.[94–97] Given the short notice (typically a few days) between the announcement and the actual meeting date, it is unlikely that these speakers underwent the formal conflict-of-interest screening typically required of AC members. The "expert panels" thus elude accepted safeguards for transparency and public accountability and instead appear to uplift expert opinions aligned with the administration's preconceived ideas. Regardless of whether or not these expert panels, as constituted, rise to the definition of an AC under FACA, these expert panels should represent balance in viewpoints, and the agency should still aim to adhere to standardized AC processes for vetting their invited experts for conflicts of interest.

FDA SHOULD PROACTIVELY AND MORE FULLY DISCLOSE DOCUMENTS RELATED TO INSPECTIONS

Both routinely and in response to complaints, FDA performs inspections of facilities producing FDA-regulated products. Form 483s are issued to establishments at the end of the inspection if officials observe potential violations of federal regulations.[98] Establishment Inspection Reports (EIRs) are documents prepared by inspectors after the close of the inspection, and include final inspection statuses (No Action Indicated [NAI], Voluntary Action Indicated [VAI] or Official Action Indicated [OAI]) issued by either OII or the appropriate Center.[99] A redacted narrative summary of the EIR is proactively shared with the inspected entity.[100] Although FDA may disclose Form 483s or EIRs if it anticipates or experiences a high level of public interest or in response to a FOIA request, generally, neither document is proactively disclosed to the public. Instead, only final inspections statuses are posted in FDA's inspection database, which is updated weekly.[101] This practice could be updated to proactive disclosure through FDA policy change.

FDA SHOULD DISCLOSE THE EXISTENCE AND RESULTS OF SAFETY INVESTIGATIONS

The FDA Adverse Event Reporting System (FAERS) compiles spontaneously reported drug and biologic adverse event reports to the agency from manufacturers (which are required to report), consumers, and health care providers. A database with this information is available on FDA's website. CDER and CBER then use this information, in combination with other data available to them, to release a quarterly list of "potential signals of serious risks" and "new safety information identified from the FAERS database" on its website.[102] Here, FDA very briefly describes its current action regarding the potential signal, usually that it is "evaluating the need for regulatory action."[103] Even when these statuses are updated, details of the agency's efforts to investigate these potential safety signals are sparse. While the details of an ongoing investigation can be withheld under FOIA Exemption 5 (deliberative process),[104] once a review is complete, we recommend it be disclosed.

Providing such details is critical if the actions the agency may take as a result of an investigation are to be understood. In a 2022 study, researchers attempted to find published evidence justifying the agency's regulatory actions on safety signals in 2014-2015 but succeeded in only 22% of cases.[105]

Additional transparency concerns involve FDA's Sentinel Initiative, which was launched in 2008 to fulfil new pharmacovigilance mandates under FDAAA, predominantly making use of administrative claims data, along with electronic health records.10 FDAAA gave the agency the authority to mandate postmarket studies for approved drug products at the time of approval.[10] When FDA considers the use of Sentinel to monitor safety in that setting, that determination is typically disclosed publicly in a memo available on the Sentinel Initiative website or included in the drug's approval package. In contrast, when safety signals are identified by FDA through postmarket pharmacovigilance activities such as FAERS, and the agency assesses the feasibility of using Sentinel for additional safety evaluations, those feasibility determinations are generally not disclosed publicly.

In the food safety space, FDA maintains an analogous website for reassessment of chemicals in the food supply, although these are typically identified after the additive has been marketed for a while. The agency itself may choose to reassess a chemical or external stakeholders may request such a review.[106] Similar to drugs and biologics, FDA shares information on its webpage about the status of the review, but, unlike drugs and biologics, the Human Foods Program provides more detailed information about its findings and ongoing risk mitigation processes, if it finds such steps are needed.

For devices, manufacturers are required and the public is similarly invited to report safety concerns to the Manufacturer and User Facility Device Experience (MAUDE), but, unlike for drugs, biologics, and foods, an accounting of pending safety investigations and their resolutions is not publicly available.

TRANSPARENCY CAN BE ENHANCED WITH APPROACHES BEYOND DOCUMENT DISCLOSURES

Numerous opportunities for enhancing transparency exist outside the disclosure of product-specific documents. For example, FDA prepares many annual reports and reports to Congress with content that adheres to the requirements of the law requiring the reports, rather than considering more fully what would be helpful to the public. These reports, which are made available to the public, may include the raw numbers specified in statute, but not the rates of events, which might be more useful to individuals reporting on or studying these data. Similarly, annual reports often do not include information from previous years, making it more difficult for the public to discern trends over time without combining years of reports and analyzing them oneself.

Transparency challenges also extend to how documents related to product approvals are organized and accessed. These documents may be scattered across various agency web pages, making the retrieval and analysis of such information an inefficient and difficult process.[107] For example, labels, approval letters, and review documents about approved drugs are housed in the Drugs@FDA database, but its interface is limited to single-drug queries by name. The database does not support bulk downloads or advanced searches by drug attributes, such as number of pivotal studies in the approval. These limitations result in the need to devote significant time to manually locate and download large files from multiple pages. A simple but impactful step toward transparency would be for FDA to integrate all public documents about approved drugs into an upgraded Drugs@FDA database capable of advanced searches and downloads.[107]

Another barrier to transparency is the manner in which FDA presents data. Reports often present data in great detail, sometimes without Executive Summaries and without drawing conclusions about what the data demonstrate. Agency officials sometimes defend this practice on the ground that it is their role to merely report the requested data, not interpret it, but the agency staff are best placed to offer those interpretations, given that they understand the strengths and limitations of the data better than anyone. At a minimum, FDA should convert all public materials from PDFs to machine-readable versions that are more easily analyzed by large-language models (LLMs), an effort that aligns with FDA Commissioner Makary's stated goal of using artificial intelligence resources to improve the agency's efficiency and effectiveness.[107]

Such efforts represent a more limited approach to transparency than product-specific document disclosure and would require officials compiling the reports to keep transparency in mind as they prepare them. This would also require a degree of creativity on the part of report writers and thorough consideration of what the public might find useful, rather than simply adhering to the literal language employed by legislators. But they do represent opportunities for enhanced transparency that can be instituted today and do not require statutory or regulatory change. By more fully disclosing its materials, the agency could better inform the narrative over its activities.

FDA should also consider whether it is in possession of datasets that it could disclose. For example, in 2013, FDA issued a Request for Comments on the availability of masked and de-identified non-summary safety and efficacy data.[108] These datasets are prepared by FDA staff using data from sponsors' medical product applications, after masking to remove personal, company, or product identifiers. For example, the placebo groups of trials of treatments for similar conditions could be combined to yield a natural history cohort for that disease,[108] in turn identifying potential endpoints for clinical studies and aiding with sample size calculations in future studies of that disease. Such data are subject to FOIA and so, narrowly, the only matter at issue in that Request for Comments was whether FDA would proactively disclose the availability of such datasets. Doing so would be helpful as, without proactive listing, the public is unable to request access. However, after receiving comments on the proposal, the agency took no further action.

The COVID-19 pandemic presented further opportunities for transparency when several drug, device, and biologic products were introduced for emergency use, and public attention was heavily focused on the agency. Unlike the standardized approval packages released by FDA when approving new medical products outside of a pandemic, the rationale behind Emergency Use Authorizations (EUAs) during the early days of the COVID-19 pandemic were not communicated with the same detail and consistency by the agency.[109] Approval packages for products approved under standard procedures may be several hundreds of pages long, but EUAs early in the pandemic were substantially shorter. For example, the EUA for hydroxychloroquine (revoked about 6 weeks after it was approved), was a mere 8 pages.[110] This brevity came at a time when the public was primed for suspicion of political interference in agency review and concerns that EUAs were either being issued too rapidly or too slowly.[111] Here, as in many other areas discussed in this report, increased transparency can help alleviate suspicion. EUAs would enhance public confidence if they were accompanied by a detailed summary of FDA's decision-making process, including any internal disagreements, the supporting evidence base, and a description of any meetings held with non-FDA entities.[109] Separately, FDA can use the AC process, even after issuance of an EUA, to further explain its thinking.[109]

FDA SHOULD CORRECT MISLEADING INFORMATION RELATED TO THE PRODUCTS IT REGULATES, TAKING INTO ACCOUNT DEVELOPMENTS IN THE LAW AND THE IMPACT OF SOCIAL MEDIA

FDA's role in promoting public health extends beyond the initial assessment of regulated products.[112] It can include addressing misleading information, particularly from biomedical and pharmaceutical companies, that may distort perceptions of product effectiveness and safety. There is limited precedent for such FDA action. In 1980, the manufacturer of the gout medication sulfinpyrazone (Anturane) sought approval for a supplemental indication of preventing sudden death in the first six months following a myocardial infarction. Despite an AC's recommendation for approval, FDA denied the application on the ground that the data supporting the drug were not adequate.[113] In response, the drug sponsor released a public statement disagreeing with FDA's decision and vouching for its data.[113] In a rare action, two FDA scientists, in a detailed critique published in the *New England Journal of Medicine*, expounded on the agency's refusal to approve the drug based on flaws in the study's design and execution.[114] The FDA scientists described the cause of death classification used by the company in the study as "hopelessly unreliable."[114] They also criticized determinations by the researchers that some patients in the sulfinpyrazone group who died were "ineligible", while including patients with similar clinical histories in the control group.[114]

More recently, in 2016, FDA commissioner Robert Califf (2016-17, 2022-25) publicly criticized a 2013 publication in the Annals of Neurology[115] of a clinical trial for the drug eteplirsen (Exondys 51), manufactured by Sarepta. In an internal memorandum, later released to the public, Commissioner Califf first stated that the published findings did "not withstand proper and objective analyses of the data" and noted that the sponsor "exhibited serious irresponsibility by playing a role in publishing and promoting selective data."[116] Commissioner Califf and another FDA scientist went on to publish a letter in the same medical journal, describing its conclusions as "incorrect" and unsuccessfully urging the publishing journal to either correct or retract the article.[117]

In these instances, FDA was able to publicly respond because the product was already approved (eteplirsen) or had been discussed in a public AC meeting (eteplirsen and sulfinpyrazone). However, the agency has traditionally remained silent regarding unapproved products or those not brought to an AC, because of its historical unwillingness to acknowledge the existence of pre-market applications. With FDA's recent decision to release CRLs for unapproved products, implicitly acknowledging the existence of some NDAs, it remains to be seen whether the agency will also change its approach to addressing potentially misleading information shared by manufacturers prior to approval.

Another bold, and ultimately contested, example of FDA's attempt to publicly correct misleading information came during the COVID-19 pandemic and reflected the increasing role of social media in both informing and misinforming the public. As unsubstantiated claims of the effectiveness of the drug ivermectin (more commonly used in animals than humans) to treat COVID-19 proliferated, FDA tweeted, "You are not a horse. You are not a cow. Seriously, y'all. Stop it."[118] The tweet amassed nearly 106,000 likes.[119] FDA was sued over the post by three doctors who claimed that the tweet, and two others like it, had interfered with their medical practices.[120] The Fifth Circuit Court of Appeals eventually ruled that the agency, by suggesting physicians should not prescribe ivermectin, had exceeded its authority by giving medical advice.[120] While the agency admitted no wrongdoing, it ultimately settled the case by agreeing to remove an FDA Consumer Update advising against ivermectin use for the treatment of COVID-19 and the social media posts in question.[121] FDA officials internally lauded the "edgy tweet" in combatting misinformation,[122] but the result of the lawsuit may have had a chilling effect on FDA's willingness to address misleading information.[123]

These examples make clear that FDA is capable of publicly addressing misleading information. At a minimum, the agency should develop clear policies, consistent with its legal authority and within the bounds of the first amendment, describing how it will respond in such situations.[124] It makes little sense for an agency to so assiduously police the exact language companies may use for marketing but to then sit by as misinformation about that same product accrues. With sufficient resources, FDA should establish a team that specializes in identifying and countering misleading or inaccurate information related to the products it regulates.

FDA SHOULD TAILOR ITS TRANSPARENCY EFFORTS TO CONSIDER THE INTENDED AUDIENCE

The published medical literature supporting FDA transparency, including the previous *Blueprint*, is largely oriented toward the perspectives of advocates and researchers. While these audiences remain important, transparency from the agency must take other audiences into account, including journalists and, ultimately, the general public. Information intended for the general public, whether released directly to the public or via media outlets, should always be provided with context; disclosure of information without appropriate context has the potential to be harmful or misleading.

For example, disclosure of adverse event reports, without appropriate context, could mislead the public regarding a product's risk, as was possibly the case in 2012 with injury reports associated with highly caffeinated energy drinks.[125] In this instance, injury reports associated with energy drinks were released by FDA, but the agency provided little information beyond the product and the outcome. A story in the *New York Times*, while acknowledging that injury reporting did not necessarily establish that the product in question was responsible for the event, might have been reported differently (it's title was "Caffeinated Drink Cited in Reports of 13 Deaths")[125] had the agency provided the full narrative reports for the most serious outcomes as well as additional fields including concurrent drug use and pre-existing medical conditions.

FDA communications with media outlets offer important opportunities for enhanced transparency. Several career reporters specializing in FDA told us in interviews that their communications with FDA were often insufficiently detailed or evasive, with responses to press questions coming in technical jargon indecipherable to even these expert reporters. They reported that sister agencies with similar regulatory responsibilities were more forthcoming than FDA. However, recent cuts to FDA communications teams will necessarily undermine any efforts for improved media communications, and therefore, communications with the public.[126]

FDA CAN LEVERAGE SEC DISCLOSURE REQUIREMENTS TO INCREASE INDUSTRY TRANSPARENCY

While most attention in medical product transparency is understandably focused on FDA actions and its related statutes and regulations, US securities regulations provide an additional point of leverage that does not involve FDA directly. These laws require publicly-traded companies to disclose information when there is "a substantial likelihood that a reasonable shareholder would consider it important."[127] In one case, the SEC reached a $4 million settlement with a company that had failed to disclose that FDA had recommended an additional clinical trial for its new drug.[128]

There is some empirical evidence that SEC requirements do have an impact upon transparency practices. In a study examining CRL disclosure, completed before FDA's recent actions to release CRLs, press releases from publicly traded companies were more likely to communicate the content of such letters than companies that were not publicly traded.[22] Smaller companies were also more likely to disclose,[22] possibly because disclosure of an FDA decision not to permit marketing would be more relevant for smaller companies, with few potential products, than larger ones.

CRLs are perhaps the most relevant regulatory communication for shareholders of publicly traded companies. Given FDA's recent actions to disclose CRLs, FDA should also consider whether additional disclosures of documents in the product approval process (e.g., refuse-to-file letters) could also be of material interest to shareholders. Expanding access to these documents would further support informed investment decisions in the biopharmaceutical industry.

FDA SHOULD CONDUCT ADDITIONAL RESEARCH ON TRANSPARENCY

Increased legal document disclosure by the agency will take time to implement. In the interim, FDA officials can research and report in aggregate their findings on some aspects of the medical product review process, as has been done in the past. By aggregating data on documents currently shielded from disclosure, and removing company and product identifiers, the agency has been able to shed considerable light on the nature of the documents being withheld. Several studies identified in our literature review[22,41,72,87] and a 2024 FDA analysis[129] were conducted using such data.

In one of these studies published prior to FDA's action to release CRLs, the agency analyzed the content of CRLs and whether that content was made public in press releases or SEC filings from the sponsors.[22] From 2008 to 2013, only 14% of statements in CRLs appeared in press releases.[22] Most of the CRLs (87%) cited deficiencies in safety, efficacy, or both, yet only 15% of statements on safety and 16% of statements on efficacy in the CRLs appeared in press releases.[22] In a subsequent analysis of more than 100 CRLs for BLAs, FDA found that manufacturing facility deficiencies were the fasted growing issue cited for non-approval amongst the CRLs reviewed.[129]

In a similar study on 103 refuse-to-file letters issued from 2008 to 2017, 84.5% of agency refusals were due scientific concerns, with 30% of refusals related to drug safety and efficacy deficiencies and 19% related to drug quality deficiencies.[72] Yet, only 16% of companies disclosed the issuance of the refuse-to-file letter, and these companies only disclosed 5% of the reasons FDA cited for refusing their products.[72] Even with the disclosure of CRLs, FDA should, at a minimum, disclose aggregated data on the number of products not approved each year and describe the reasons for these rejections.[88] These sorts of studies redound to the agency's benefit when the research demonstrates, for example, that FDA's reasons for CRL issuance are grounded in substantial safety and efficacy issues and not on trivial concerns.[22,72]

FDA SHOULD CLOSE THE GRAS LOOPHOLE FOR FOOD CHEMICALS

As described in the Findings of this report, the voluntary process by which companies notify FDA of food chemicals they deem "GRAS" results in a system stark in its lack of transparency, where industry's self-attestations of safety are not routinely provided to FDA or the general public.

There are several ways to close or narrow this loophole. The most sweeping strategy would be to eliminate the GRAS option entirely for all new chemicals, and instead, require companies to submit food additive petitions and obtain premarket approval before new chemicals can be added to foods. For example, Senator Ed Markey's Ensuring Safe and Toxic-Free Foods Act of 2025 and Representative Rosa DeLauro's Toxic Free Food Act of 2024 would make new food chemicals ineligible for GRAS status.[130,131]

If the GRAS process cannot be fully eliminated for new chemicals, the process could instead be made more rigorous. For example, FDA's voluntary GRAS notice and premarket review process could be converted into a more thorough and mandatory process. Representative Frank Pallone's GRAS Act, introduced in 2025, would require companies to submit a GRAS notice and demonstrate that their food chemical is not carcinogenic while also providing the public with an opportunity to comment.[132] This particular bill does not require FDA to review the submissions, although the agency must respond to the submission within 180 days.[132]

An alternative would be for companies to be required by statute to publicly submit GRAS notices and substantiating information to a regulatory body. In 2025, New York state introduced legislation that would do just that. Those notices would then be listed in a public database, although there would be no requirement for the state to review them.[133]

Short of enacted legislation, FDA itself can take regulatory action to implement some of these reforms by amending its 2016 voluntary GRAS rules to require both premarket GRAS notice and agency review. While the FAA exempts GRAS substances from the food additive petition process, it does not dictate a process for FDA to designate a substance as GRAS.[53] Thus, the agency could revise the 2016 rule to not permit companies to self-certify unapproved additives as GRAS.

Secretary Kennedy's directive to FDA to explore requiring notice and public listing before a GRAS chemical can be used in food appears to stop short of requiring that FDA review whether those notices have sufficient evidence to establish the chemical as safe.[33,134] While notice is a necessary step, a transparent FDA fulfilling its public health mandate would also vet such notices.

FDA SHOULD PRIORITIZE IMPLEMENTATION OF TRANSPARENCY RECOMMENDATIONS THAT FALL WITHIN ITS EXISTING AUTHORITY

Table 2 summarizes the changes necessary to put into place the 17 unimplemented recommendations in the *Blueprint* and the 15 additional recommendations contained in this report. Depending on the proposal, implementation might require statutory change, regulatory change, policy change, or a mere change in internal FDA norms. In our assessment, none of these recommendations with certainty requires a statutory change, although in 16 cases (50%) it might be required and, if attained, would greatly clarify disclosure requirements. In 14 cases (44%), a regulatory change would be required, but in at least 10 cases (31%; e.g., disclosure of the Section 502 conflicts of AC members [Table 2, Recommendation 23] and release of masked and de-identified pooled data sets [Table 2, Recommendation 26]) a simpler change in policy would be all that is necessary to permit disclosure. For three recommendations (9%; e.g., including summary statistics on required reports [Table 2, Recommendation 23]), FDA would only need to change its internal norms.

Notably, as described in our Finding detailing the outcomes of the *Blueprint* recommendations, our legal analysis found that FDA should update regulations to provide clear authorization for the release of CRLs—including those for products whose applications have not been acknowledged by the sponsor. We support the release of CRLs as an important transparency measure, but this action should be supported by regulation.

Conclusion

In addition to the 17 unimplemented recommendations described in the *Blueprint*, we recommend 15 actions to be taken by FDA, for a total of 32 recommendations, to improve transparency, increase public trust, and ultimately improve the safe and effective use of medical products by patients.

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